



EXPLORING THE CHALLENGES & designing potential solutions for INSULIN PUMP TECHNOLOGIES

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5-STAGE PROJECT METHODOLOGY

Phase 1: Background Research

- Literary research
- Market Research

Phase 2: Field Research

- Online Survey
- Interviews
- Participatory Design Workshops

Phase 3: Design & Development

- Design Criteria
- Benchmark Existing devices and interfaces
- Iterative sketching
- CAD modeling
- Digital prototyping

Phase 4: Usability Testing

- Remote user tests and test findings
- Discussion and moving forward

ABSTRACT

This study examines the current technology of diabetes management devices, primarily insulin pumps. Insulin pumps are effective tools for the precise control of glucose levels, for type 1 diabetes (T1D) patients. Many design and usability challenges still exist with insulin pump technologies. In this study, we investigated current shortcomings and limitations of insulin pumps through survey and interview data collection methods. Our findings revealed issues with current insulin pumps including:

- 1) wear-ability and accessibility in public*
- 2) operating devices while performing demanding tasks*
- 3) interruptions with social activities and interactions*
- 4) continuity of maintenance, and*
- 5) interface operations.*

Using the data from our investigative work, we produced design criteria to develop a novel wrist-worn interface and separate pump design for a closed loop artificial pancreas system. We then evaluated the design through seven remote usability testing sessions with insulin pump users. Our study aspires to inform the future design of novel insulin pumps that enable people with T1D to maintain better control of their glucose levels through consistent and steady interactions with these tools during their everyday activities.

GLOSSARY OF COMMON DIABETES RELATED TERMS

A1C
A blood test that measures a person’s average blood sugar level over the past 2 to 3 months. A normal A1C level is 5.7% or lower. People with diabetes may have an A1C of 6.5 or higher. The goal for most people with diabetes is to have an A1C of 7% or less.

Artificial Pancreas System (also known as a closed loop system)
A device network consisting of a continuous glucose monitor and insulin pump. The continuous monitor tracks glucose levels and sends that data to the insulin pump, so the pump can automatically deliver the appropriate amount of insulin.

Autoimmune disease
A disorder where the body’s immune system mistakenly attacks its healthy tissues. In the case of diabetes, the immune system attacks the pancreas’ beta cells which produce insulin.

Basal Insulin
A small steady flow of insulin that is always present in the body, primarily while fasting between meals. In people without diabetes, this is known as basal secretion. People with diabetes must either inject a long-lasting insulin that replicates basal secretion, or program a basal rate using an insulin pump.

Blood Glucose Level
(also referred to as blood sugar level) refers to how much glucose is in the bloodstream at a given time. This level is very important for people with diabetes, and they must monitor their blood glucose level throughout the day. If the blood glucose level is too high, there isn’t enough insulin in the blood. If it’s too low, there’s too much insulin.

Blood Glucose Meter
a small, portable device used by people with diabetes to check their blood sugar levels. After pricking the skin with a lancet, one places a drop of blood on a test strip in the meter. The device soon displays the blood sugar level as a number on the digital display.

Bolus Insulin
After a meal, the pancreas releases the right amount of insulin to process the carbohydrates in the meal. This is known as bolus secretion. People with diabetes must calculate a dosage of insulin based to the grams of carbohydrate in the meal, known as a bolus.

Continuous Glucose Monitor
A small wearable device, usually worn on the abdomen, with a sensor that penetrates the skin. This device is able to take glucose readings every few minutes, throughout the day. The continuous glucose monitor also utilizes a transmitter, which sends glucose readings to a separate monitor or smartphone app.

Correction Bolus
A bolus that is taken in order to correct a high blood glucose level.

Carbohydrates
one of the three main nutrients in food. Foods that provide carbohydrate are starches, vegetables, fruits, dairy products and sugars.

Carbohydrate Counting
a method of meal planning for people with diabetes, based on counting the number of grams of carbohydrate in food.

Diabetes Mellitus
a condition characterized by hyperglycemia resulting from the body’s inability to use blood sugar for energy. In Type 1 diabetes, the pancreas no longer makes insulin and therefore blood sugar cannot enter the cells to be used for energy. In Type 2 diabetes, either the pancreas does not make enough insulin, or the body is unable to use insulin correctly.

Diabetic Ketoacidosis (Ketosis)
An emergency condition in which extremely high blood glucose levels, along with a severe lack of insulin, result in the breakdown of body fat for energy and an accumulation of ketones in the blood and urine. Signs of ketosis

include nausea, vomiting, stomach pain, fruity breath odor, and rapid breathing. Untreated ketosis can lead to coma and death.

Insulin
a hormone that helps the body use glucose for energy. The beta cells of the pancreas make insulin. When the body cannot make enough insulin, it is taken by injection or through use of an insulin pump.

Insulin Pump
an insulin-delivering device about the size of a deck of cards that can be worn on a belt or kept in a pocket. An insulin pump connects to narrow, flexible plastic tubing that ends with a needle inserted just under the skin. Users set the pump to give a steady trickle or basal amount of insulin continuously throughout the day. Pumps release bolus doses of insulin (several units at a time) at meals and at times when blood sugar is too high, based on programming done by the user.

Meal Bolus
An insulin bolus taken before a meal.

Neuropathy
disease of the nervous system. The three major forms in people with diabetes are peripheral neuropathy, autonomic neuropathy, and mononeuropathy. The most common form is peripheral neuropathy, which affects mainly the legs and feet.

Retinopathy
An eye disease that is caused by damage to the small blood vessels in the retina. Loss of vision may result. (Also known as diabetic retinopathy)

Target Range
Blood glucose levels need to stay within a certain range, and when you have diabetes, you must regulate your blood glucose levels with diet, exercise, and (perhaps) insulin. Before meals, the target range is 70 to 130mg/dL, and one to two hours after a meal, the target range is below 180mg/dL.

COMMON ABBREVIATIONS

APS	Artificial pancreas system
BG	Blood glucose
CGM	Continuous glucose monitor
Carbs	carbohydrates
DKA	Diabetic ketoacidosis
High	High blood glucose
Low	Low blood glucose
T1D	The common abbreviation used for Type One Diabetes.

PHASE I: BACKGROUND RESEARCH

Literary Review, Market Research

INTRODUCTION AND RELATED WORK ON INSULIN PUMPS

Insulin pump technology has advanced rapidly over the last decade. Major pump makers are introducing the first Food and Drug Administration (FDA) approved closed loop architecture, matching the pump with a Continuous Glucose Monitor (CGM), where the devices communicate via Bluetooth. This device network simulates the characteristics of a pancreas to regulate glucose levels more accurately. The Dexcom mobile application allows users of their proprietary CGM to track and share real-time glucose data with, designated family members and healthcare providers [1].

Pump interfaces have begun to diverge from the more traditional mechanical buttons and display. Touchscreens are being implemented in some newer designs, either integrated on the pump itself, or accompanying as a wireless controller. While touch screen interfaces are becoming more popular in insulin pump design, they still pose some limitations to users as they rely heavily on ‘eyes-on’ interactions. Haptic features (e.g. mechanical buttons) can play an important role in operating insulin pumps by facilitating eyes free interactions [2], but their value may be underestimated.

Additionally, people with impaired vision may have trouble using touch screens and must use other methods for managing diabetes. For example, some have elected to use V-Go which was designed for people with Type 2 diabetes. Since the device’s interface consists of three buttons, and doesn’t make use of a digital display, it can be operated without any visual cues. However, it has limitations: basal rates cannot be changed, and the device can only deliver one 2-unit bolus at a time. People with T1D often need much more precise dosage increments to properly manage glucose.

Other researchers have conducted studies on the design and human factors aspects of insulin pumps. For

example, Tandem Diabetes researchers referred to their process as “prevention through design” and worked with end-users to test user perceptions and viability of the pump’s interface, to determine what information should be present on various screens and calculate health risks that may occur during specific interactions with the pump [3]. While companies like Tandem are making strides to ensure their products are safe and easy to use, there is still a need for further research and development on the usability of insulin pumps.

Due to the nature of challenges and the lack of concrete solutions, hacking into the system software of insulin pumps became increasingly popular in the diabetes community. For example, Dana Lewis [4] started modifying her pump and CGM, to make her alarms louder in case she experienced dangerously low glucose levels at night. This led to developing a simple algorithm that could forecast glucose levels and make dosage corrections. This work has been shared with the open-source community, which initiated #OpenAPS (Open Artificial Pancreas System) [5]. Lewis and Leibrand [6] later explored Open APS systems effectiveness and participants reported reduced average glucose levels, spent approximately 40% more time within target glucose range, and all but one improved sleep [7]. Other open source systems such as the Loop mobile app (designed for automated insulin delivery) have been developed by DIYers in the diabetes community to control older insulin pumps, via a Raspberry Pi based device (RileyLink), which translates the wireless signals of the pump, CGM, and smartphone; allowing the devices to communicate [8]. The DIY community coalesced further by introducing hashtag #WeAreNotWaiting to denote the need for more rapid technological development, increased interoperability of devices, and better data exchange. DIYers continue to use the hashtag, expressing their intention to overcome regulations and the limited proprietary technologies currently available [7].

THE RILEYLINK / TIDEPOL LOOP ECOSYSTEM

How it works

RileyLink was developed, to allow a Bluetooth connection between a smartphone and a compatible insulin pump. Using the Tidepool Loop app, DIYers can control their pump via smartphone. Furthermore, the system can monitor glucose and automatically deliver insulin, without user intervention.

Open Source and the FDA

While these open source advancements have enabled people with T1D to take better control of their diabetes, the FDA has not approved any of these technologies. More specifically, the FDA has not approved of any systems where a cellular-enabled smartphone can control an insulin pump.

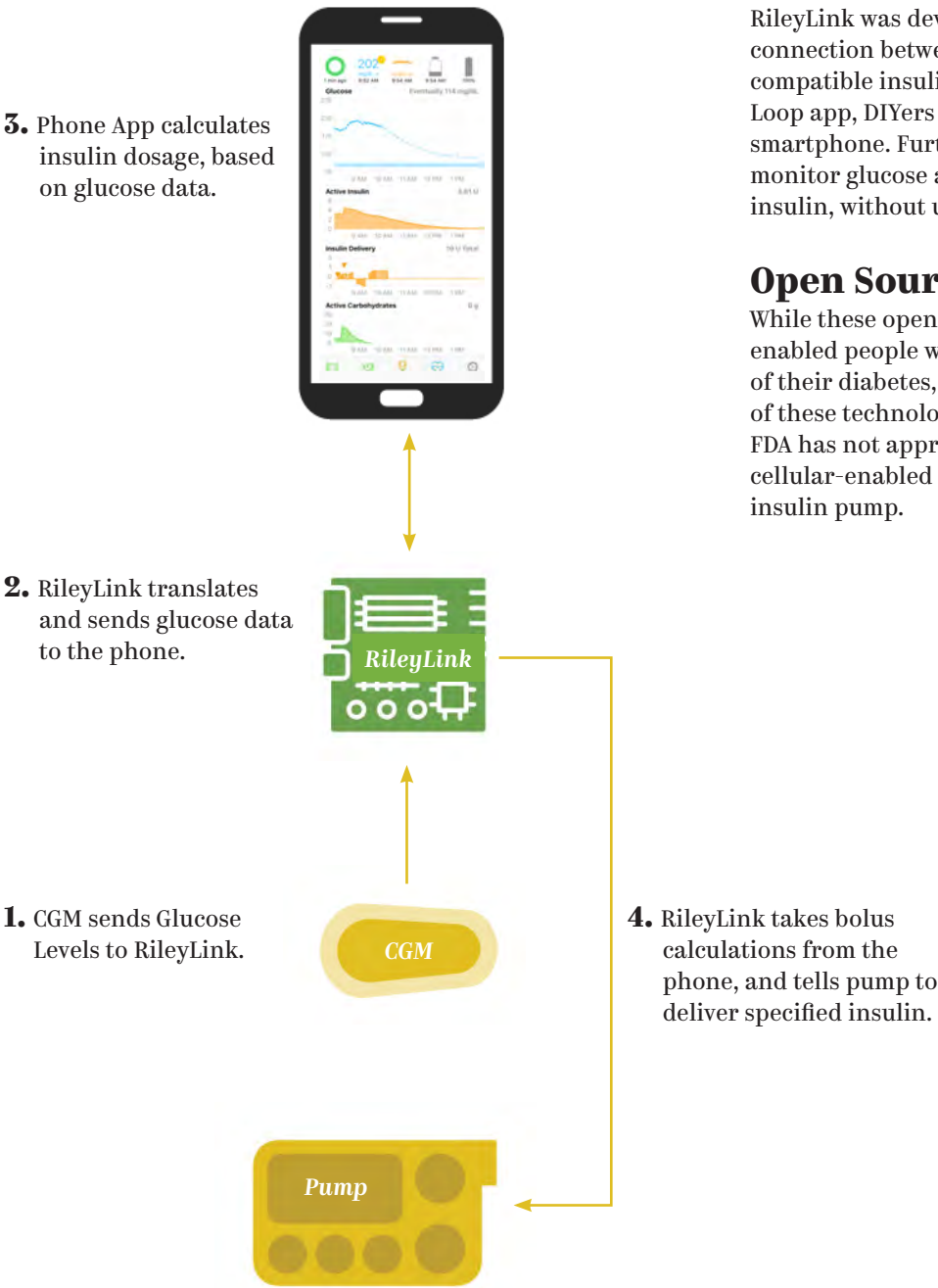


Fig 1, Graph showing the “closed-loop“ design of the rileyLink device and tidepool app

THE CURRENT STATE OF DIABETES TECHNOLOGY

Current market research helped to reveal possible design opportunities. While touchscreens are trending with devices like the Dexcom G6 receiver and T:slim X2, legacy pump designs with mechanical buttons are phasing out.

Several products exposed challenges that specific groups of people face. The V-Go pump (image 6) is designed for people with type 2 diabetes, however, it has seen some use from type 1 diabetics who suffer from vision impairment. “The V-Go is great for those who are blind but has its limitations... Exact dosing is limited compared to insulin pump therapy. Most people with type 1 diabetes require a basal other than what it provides...” [9]. The Tidepool loop App combined with RileyLink device also revealed the increasing demand for capable closed-loop systems.



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1 Medtronic 670G

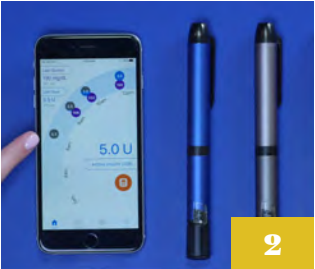
The most popular new model on the market. The 670G is also the first FDA approved Closed-loop system that comes with a proprietary CGM which requires twice daily calibrations.

2 Smart Insulin Pens

Several companies have produced smart insulin pens, which carry a several day's supply of short acting insulin. The smart pens are able to connect to smart phone apps which aggregate data like insulin on board, and blood glucose logs.

3 EverSense CGM

EverSense utilizes a microchip, implanted under the skin. The oval-shaped sensor can be taped or even waved over the chip location, to obtain glucose readings.



2

4 Dexcom CGM

The Dexcom G6 can communicate glucose data to a dedicated PDA, smartphone, or smartwatch. This device does not require calibrations, which often involve periods of fasting and checking glucose via traditional glucose meters.

5 Insulet Omnipod

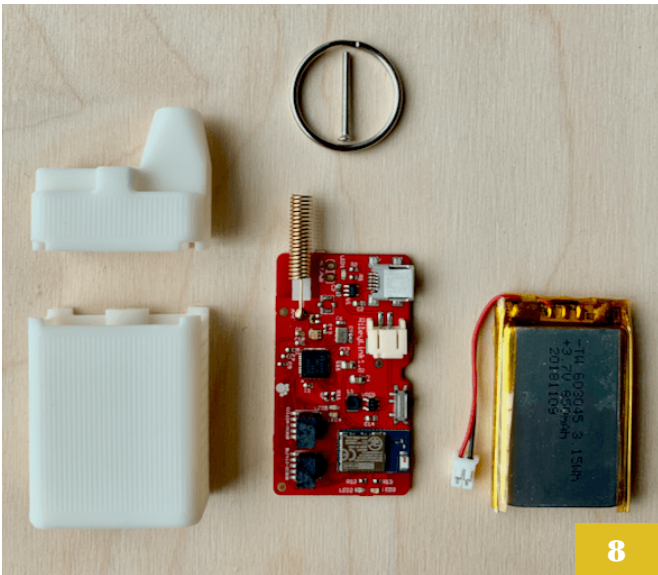
The first tubeless insulin pump design; Omnipod is controlled via a dedicated PDM with integrated glucose meter, or cellular disabled Samsung smartphone. This pump is also compatible with the Dexcom CGM, creating a semi-closed loop system.



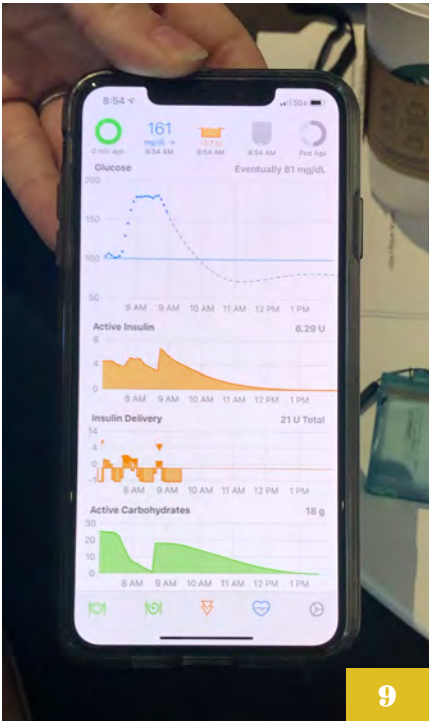
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6 V-Go

V-Go does not run on batteries. The pump is worn like a patch, similar to Omnipod. It was designed for T2D, however, it has been adopted by some T1D patients who suffer from visual impairment, such as diabetic retinopathy.

7 Tandem T:slim X2

The touchscreen Interface is the pump's unique feature. The pump advertises a compact design, and is compatible with Dexcom's CGM to create a closed loop system.

8 RileyLink

Part of the DIY movement: RileyLink is typically a raspberry pi computer, programed to link with compatible CGM's and older insulin pumps. This creates one of the first open APS closed loop systems.



10

9 Loop App

An open source app: Tidepool's Loop App enables users of the RileyLink to control compatible insulin pumps using a smartphone. The app takes the patient's carb ratios, insulin sensitivity, and correction bolus factors to precisely manage glucose levels.

10 Legacy Pumps

Some older Medtronic pumps are being adopted by DIYers. Used in conjunction with RileyLink, Loop App, and a CGM, these pumps have become part of a roots-level movement in developing new closed-loop systems.

11 Glucose Meter

The traditional approach to monitoring blood glucose. Meters require a blood sample. Newer meters can transmit glucose data to insulin pumps via Bluetooth. They are also required for calibrating some CGM's, like the Medtronic.

PUMP WEARING LOCATIONS

People tend to wear insulin pumps in areas of the body that have low flexion and movement, such as thighs and upper arms (see figure 4). Wearing locations also tend to have a larger surface area, such as the abdomen and buttocks. One reason these areas are chosen has to do with the location of the injection site. The abdomen and upper arm are considered ideal injection locations because these locations are able to absorb insulin more quickly. All of these areas are thought to have adequate fatty sub cutaneous tissues, which reduces the chance of injecting directly into muscle tissue and causing pain and irritation [10].

These common pump wearing sites are also considered ideal dynamic wearable zones (see figure 2) for electronic wearable devices. The low flexion and high surface area of the upper arm, abdomen, buttocks, and thighs make them ideal areas that help wearable devices to feel unobtrusive [11]. Something else that Gemperle, Et Al. Pointed out is that wearable devices may be considered less obtrusive and more comfortable to wear if they feature a concavity on the surface touching the body (see figure 3). This is thought to better fit the convex curvature of the human anatomy. Virtually all current insulin pumps feature a single point of attachment, such as a clip, and have a square form which may feel more separate from the body, thus more obtrusive.

Pump Wearing Locations Correlating with Gemperle’s Ideal Dynamic Wearable Zones:

- Abdomen
- Around the thighs (pockets)
- Upper Arms
- Lower Back
- Fore Arms

Fig 2, Visual Depiction of Gemperle’s Dynamic Wearing Zones

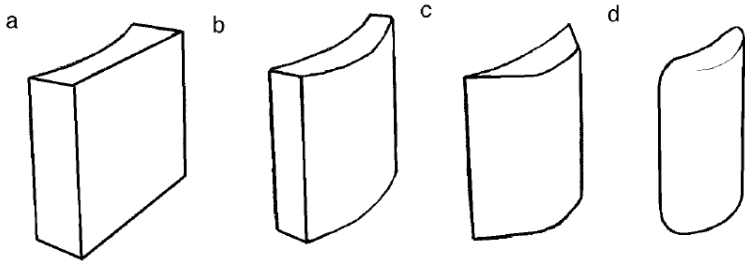
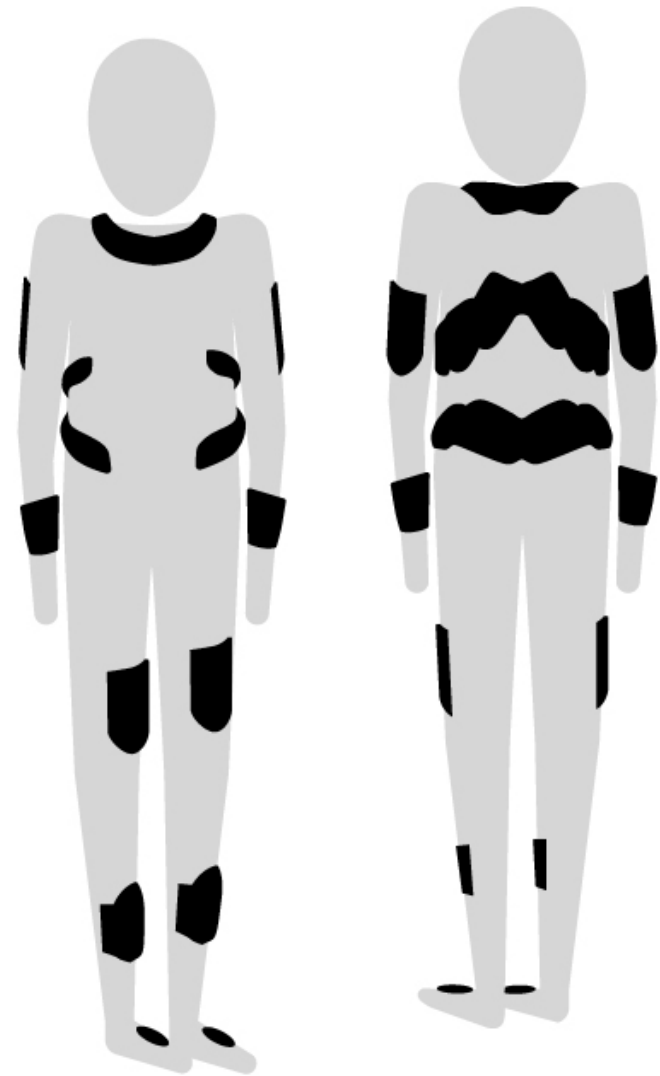


Fig 3, Gemperle’s illustration, showing the process of transforming a block to a humanistic wearable form: **A)** Concave against the body, **B)** Convex on the outside surfaces, **C)** Tapering, as the form extends off the body, **D)** softening edges to create a humanistic form language.

Fig 4, Locations Mentioned by Interviewees

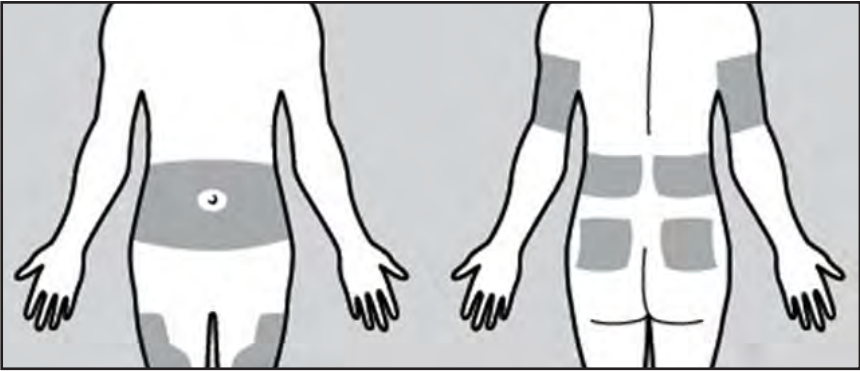
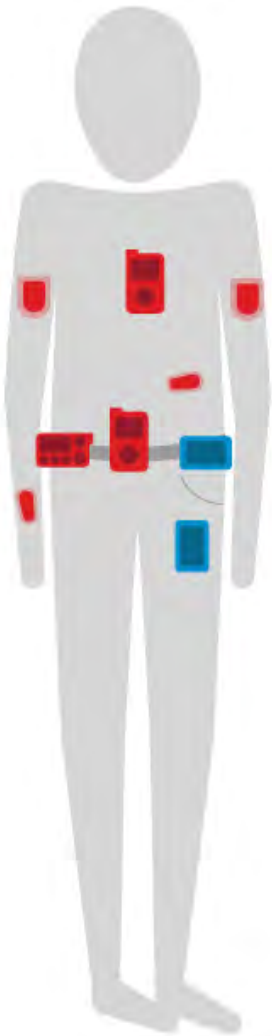


Fig 5, Ideal insulin pump infusion sites, recommended by Medtronic Diabetes

PHASE II: FIELD RESEARCH

*Surveys, Interviews, Participatory
Design Workshops*

ONLINE SURVEY

A 12-question survey was dispersed to several online forums, through JDRE, and personal contacts, which garnered 105 responses. 68 of the respondents were female, 35 were male, and 2 did not disclose gender. Average age range of respondents was 45-54.

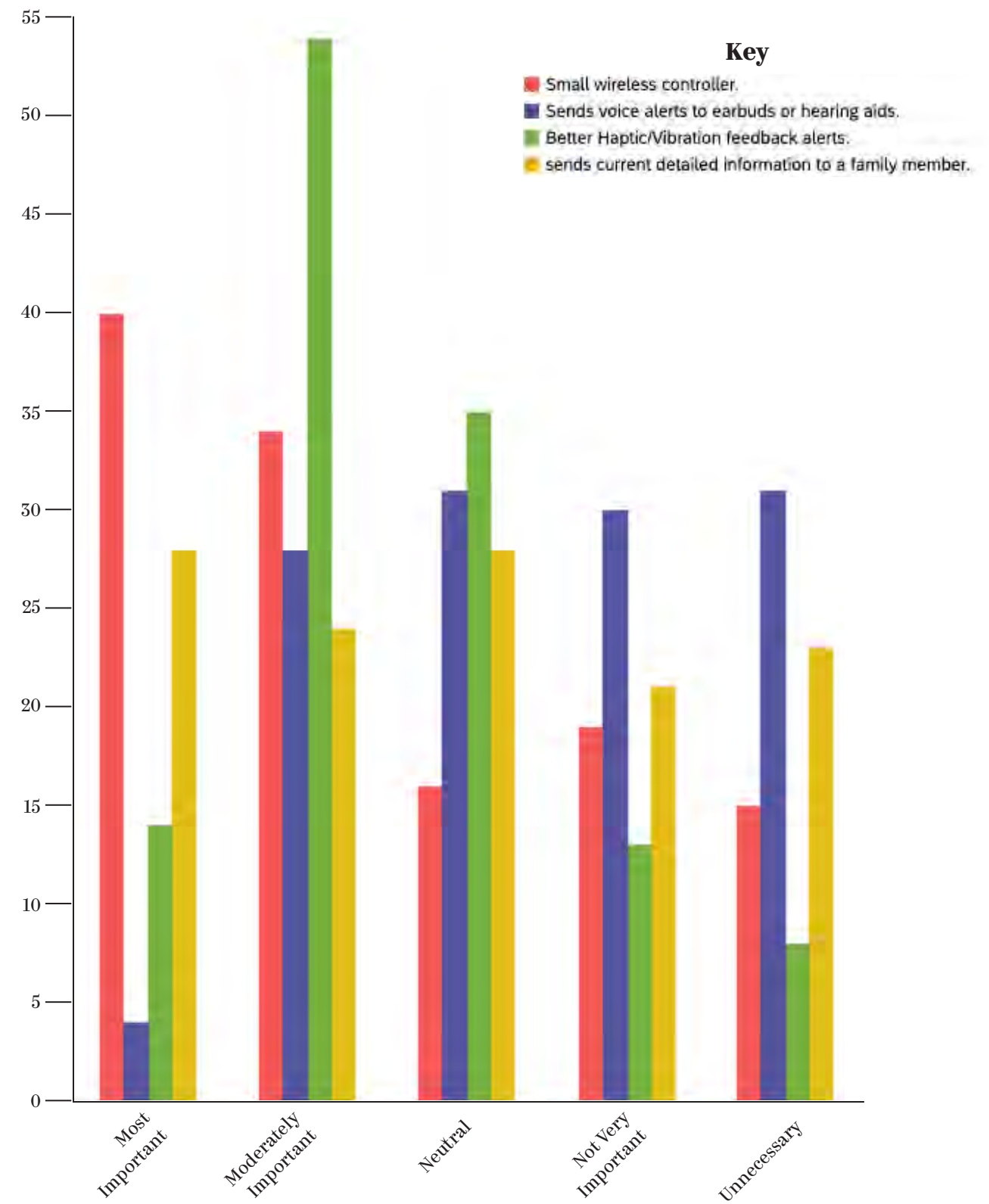
The goals of the survey were to collect a representative sample that could show how people interact with pumps, common pain points, and most desired new features they would like to see in an insulin pump. The end of the survey featured two open-ended questions, asking participants to express their deeper opinions about current technology. Participant names were coded (R1 – R105) to protect identities.

A portion of the survey focused on interacting with pumps eyes-free vs. eyes-on. The survey data showed that 30% of respondents use their pumps without looking at the screen. Roughly 12% of all respondents admitted to having difficulty reading the display on their pump interfaces.

Finally, 50% of the survey respondents revealed that they wish pumps could convey more information without having to look at the screens.

The survey mentioned four specific design features, and asked respondents to rate which features would be most important to have in a new insulin pump. Features included a small wireless controller, sends voice alerts to earbuds or hearing aids, better haptic/vibration feedback alerts, and sending current detailed information to a family member. Some of these features do currently exist. Several pump and CGM models come with a proprietary PDA-like device (e.g. Omnipod). Several mobile apps are also capable of sharing glucose levels with others. Haptic feedback was hypothesized to be a potential interaction method for people with vision impairment, as well as a universal feature for those who feel the need to operate pumps without having to look at a screen. Small wireless controllers came out as the most desired feature, followed by sending current information to a family member, and better haptic feedback. The chart to the right depicts responses to the question, “What design features would be most important for you to have in a new insulin pump?”

MOST DESIRED NEW DESIGN FEATURES FOR AN INSULIN PUMP



SURVEY: AWKWARD SITUATIONS

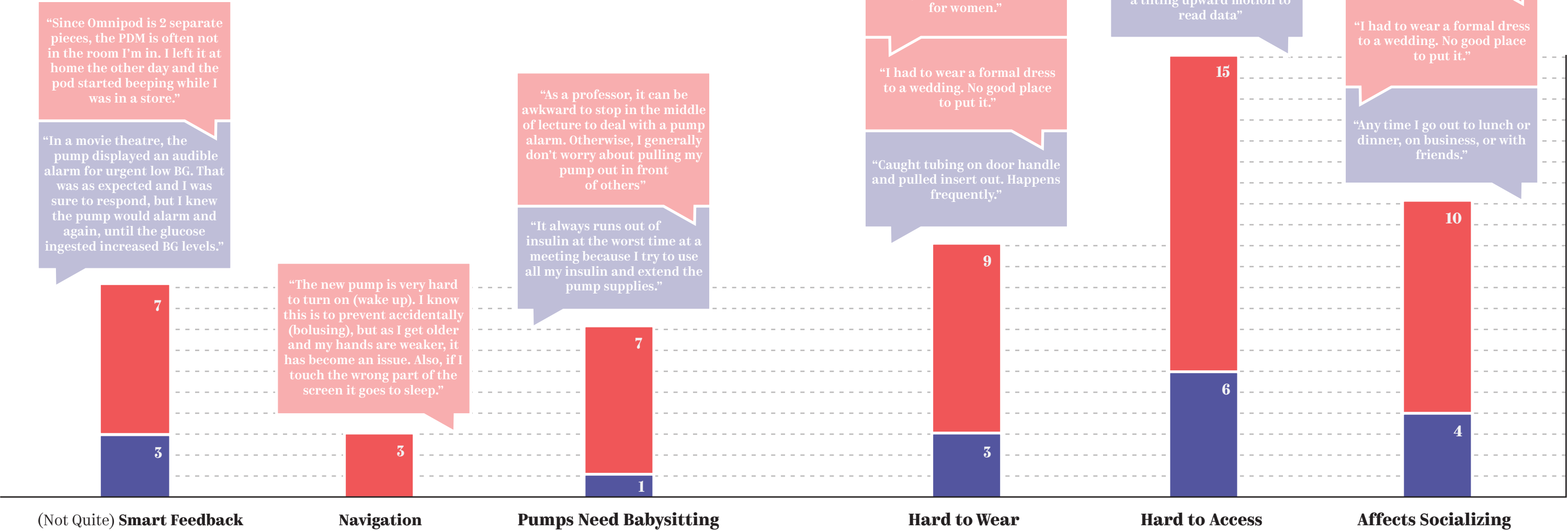
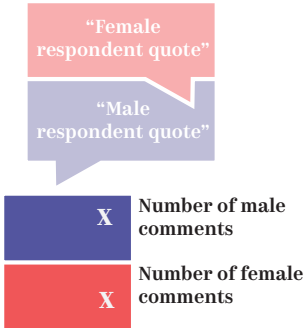
The end of the survey featured two open-ended questions, asking participants to express their deeper opinions about current technology. Answers were then organized into affinity diagrams for further analyzing. infographics in figures (XX) graphically show how each of the answers were categorized.

When asked to describe a situation where using a pump was awkward or difficult, several major themes

emerged: accessing the device interface from the person's wearing location, affecting social activities, feedback and alerts, and wear-ability. The answers revealed particular wearing challenges for women. For example, R-87 stated, "I have quit wearing dresses and skirts since it is difficult to get to my pump without having to find a bathroom. I have even gone off the pump for 24 hours so I could function easily at my son's wedding" 17 respondents specifically mentioned challenges they face regarding insulin pumps and women's clothing.

Even where pumps don't directly affect social occasions, the affinity diagrams revealed that pumps often interrupt various activities. "I often get alarms when driving. This by far is the most inconvenient time as I want to respond and, if necessary, administer a bolus. This is often very awkward." (R 35) Trying to safely access a pump while driving was mentioned 7 times. Seventeen respondents mentioned situations where pump maintenance inhibits another task, such as exercising, office work, or watching movies.

Key



SURVEY: NEW FEATURES

Respondents answered the question:
“If you could have any new feature in an insulin pump, what would it be?”

The majority of respondents expressed desires to control their pumps from a smartphone app.

Other areas included redesigning the form of the pump, streamlining navigation, and designing better alerts and feedback.



INTERVIEWS

Interviews were conducted after completion of the survey, to collect more in-depth data around participants issues with insulin pumps. Seven participants were recruited through a JDRF Facebook group and through contacts at JDRF corporate offices in Atlanta.

Participants included 5 females and 2 males. The average age range of all participants was 34-44. All interviewees use pumps and CGM's. Two of the female participants also use the Tidepool open source system. One tidepool user also suffers vision loss due to diabetic retinopathy. Participant names were coded (P1 – P7) to protect their identities.

The interview format started with introductory questions focused on pump model, wearing location, and inquiring about other 3rd party apps or products each person might use. The main section consisted of situational questions that related to using insulin pumps for routine activities, like taking a meal bolus. Final questions focused on using pumps in situations where it might be difficult to do so.

Many participants discussed issues with pump interfaces, during the situational questions. For P7, the bolus history section was a pain point. “One of my biggest complaints on this pump is the recall history. Bolus/Basal history is a very poorly organized section of the interface. Hard to tell boluses apart. No logical spreadsheet breakdowns.” Figure 6 shows P7’s bolus history screen. Some pump history sections don’t feature clear breaks between each bolus given. In P7’s example, all previous boluses appear to merge together. This may be considered a false cognitive affordance [12].

Because social situations were revealed as a strong pain point in the survey comments, interview participants were also asked to recount any socially awkward

situations relating to their insulin pumps. Several participants mentioned experiences where their pumps became a public distraction. P5 discussed one Interaction in an academic setting. “I had a professor who had a really stringent rule as far as phones. ‘If I hear your phone, you gotta’ buy donuts for the whole class...’ One day, I ran out of insulin in class. Of course, it started beeping like a madman. Long story short, it made noise and the professor said, ‘We’ve got our first phone. I guess you’re buying donuts for the whole class!’”. Regarding alerts, P7 expressed a desire for more customizable alert settings for different pump functions. “It would be good to have different customizable things for different features... Every time I’m low or high, I don’t want it beeping as loud as I want it beeping if I have an occlusion.”

Many survey respondents mentioned needing to use pumps while driving. Interview participants were also asked about using pumps while driving, which revealed further insight on these pain points. On the subject of getting pump alerts while driving, P4 stated: “I know the functions and I’m a safe driver in general. But I would just pull it out and try to take care of it at the next stoplight.” P1 mentioned pump interaction without taking her eyes off the road: “I’ve memorized functions. I bolus while driving...Like if it says I’m high, and it’s alerting me, I will lie about eating carbs just to get the bolus.” P7 discussed using a trusted passenger’s help, while driving: “A lot of the time, if I’m on a road trip, my girlfriend might be sitting in the passenger seat. And I’ll hand her the pump and be like, ‘can you give me 5 units?’” P5 also stated: “If I have someone else in the vehicle, like my brother for example. If he’s in the passenger seat, I’ll just say, ‘hey, here’s my pump.’”



Fig 6, Pump interface showing the bolus history section.

Interview Questions:

1. What make/model pump do you use?
2. Where do you typically wear your pump?
3. Do you use any 3rd party mobile applications with your pump/to manage diabetes?
4. Do you ever find it difficult to access your pump from where you wear it?
5. Can you walk me through giving a bolus?
6. Do you take any extra measures for when your pump is low on insulin?
7. What might you do if you get an alert or need to use your pump while driving?
8. Do you ever find yourself in situations where it might be socially awkward to use your pump? What have you done in those situations
9. Invitation for Questions and Thoughts

LIVING WITH INSULIN PUMPS

Interviewees often discussed the number of devices they must carry around on a daily basis. P2 may carry as many as 7 devices with her, mainly when traveling for work. Those devices include insulin pump, RileyLink transmitter, Dexcom CGM receiver, CGM wearable, smartphone using the tidepool loop app, glucose meter, and a spare syringe and insulin bottle which is kept in a cooler. Even when people with T1D aren't forced to carry a large assortment of gadgets, these devices can be bulky and cumbersome.



Figure 3, Photographs of interview participants' pumps and devices.

WEARING LOCATIONS

Figure 8 illustrates areas where each of the interview participants wear insulin pumps and related devices. Where applicable, the graph also details stories or scenarios related to wearing pumps, CGM's and related devices, highlighting some of the challenges of wearing insulin pumps.

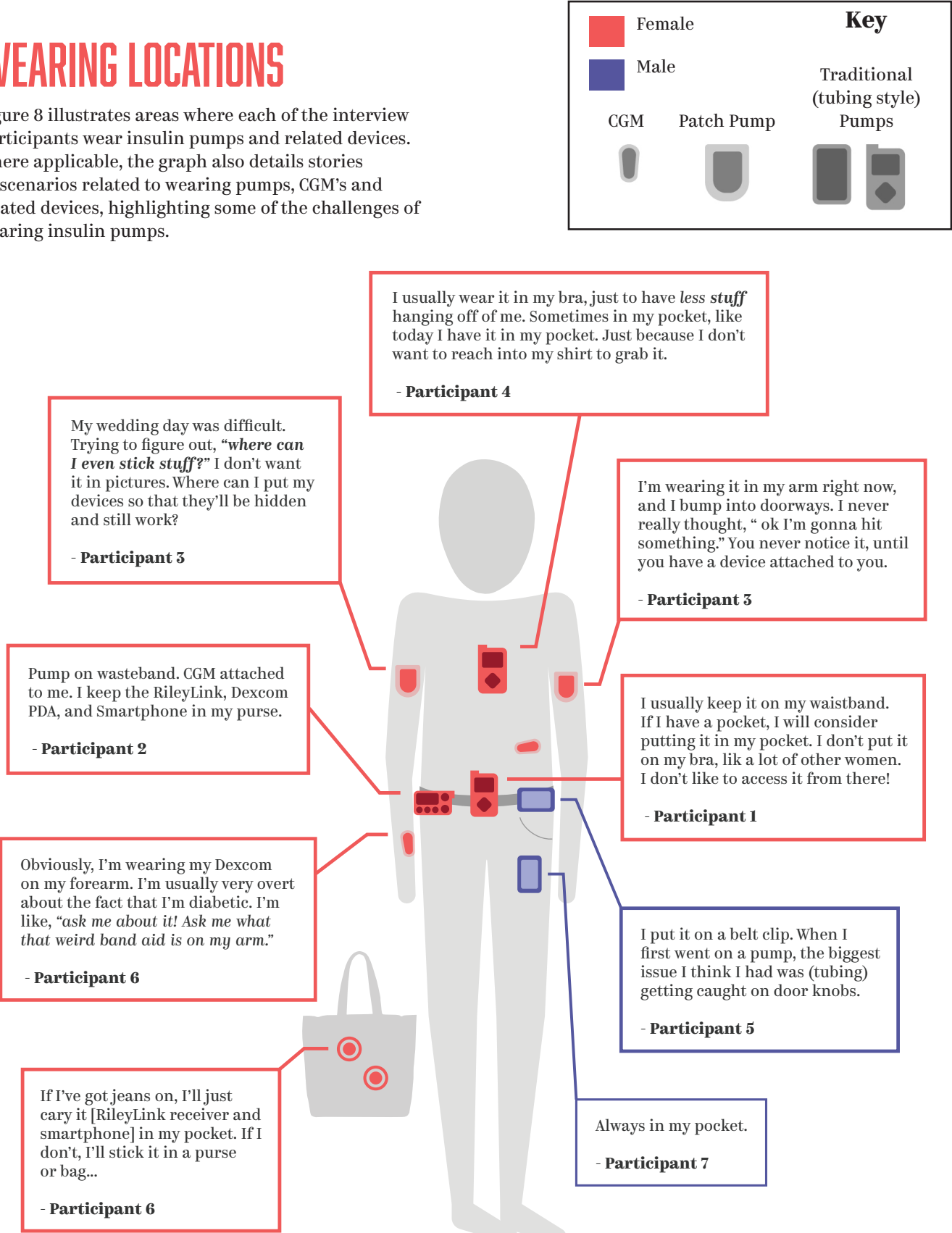


Figure 8, visual depiction of all interviewee pump wearing locations.

INTERVIEW QUOTES: AFFINITY DIAGRAM

Interview participants shared meaningful personal stories about living with diabetes and using pumps. These stories reinforced the survey findings and helped point to multiple design opportunities. Participants had the most to say about using pumps while performing demanding activities, like driving. Using pumps in public or social situations was another strong discussion topic.

Similar to the open-ended survey data, participant quotes were arranged in an affinity diagram, then distilled into the diagram.

User Interface

One of my biggest complaints on this pump is the recall history. Bolus/Basal history is a very poorly organized section of the interface. Hard to tell boluses apart. No logical spreadsheet breakdowns.

-P7

Feedback / Alerts

“in general, it just gives me too many alerts. Even during the day. If you’re not just steady on target all the time (which I would love to be) it can’t keep me there.”

-P1

“I wish that they (alarms) were more customizable for various things. It would be good to have different customizable sounds for different features... Every time I’m low or high, I don’t want it beeping as loud as I want it beeping if I have an occlusion.”

-P7

Bolusing

“Whatever algorithm is baked in, it takes into account things like my insulin sensitivity factor that I set, my carb ratios, the insulin curve based on the type that I’m using, and my glucose and how that’s changing.”

-P6

“(Eating at restaurants) I don’t bolus until I have food in front of me. I’m way too paranoid that it’s not gonna come out in time. Or I’m thinking this is gonna be 5 cups of food, and it’s really only 2 and ½ cups. Or visa versa.”

-P3

“I will say, the quick bolus on the animas ping is 10 times easier than the quick bolus on this. That’s an older design, and I used to use that all the time.”

P7

Connectivity

Using the Dexcom, I’m constantly checking. But losing the riley link the other day, I started to work myself into a panic. Because I was like, ‘I’m gonna have to go back to my receiver, and this whole thing isn’t going to work until I find it. What if it’s giving me too high of a basal rate right now? And it’s stuck on that, because I lost the thing.’ It’s anxiety inducing for sure!”

-P6

“Particularly for younger children, the app allows parents to see it as well. For that matter, I gave it to my doctor. And he could track my blood sugar whenever he wanted. Apparently, there were times where he would call someone’s parents and be like, ‘hey are you worried your kid’s having a low?’ I didn’t have the tech for it. I really didn’t want to buy an apple phone just for that.”

-P5

Low Insulin

“I always bring a backup with me, because I’ve had them leak before or just straight up fail. They start beeping and it’s awful...I’ve always got extra insulin and a syringe in my bag.”

-P6

“I know that even if my pump says I don’t have any insulin on board, I still have 15-20 units, because of the infusion set. So, if I’m not going too far outside of the general home range, I probably won’t do anything about it until I get home.”

-P4

Out In Public

“My wedding day was difficult. Trying to figure out, where can I even stick stuff. I don’t want it in pictures. Where can I put my devices so that they’ll be hidden and still work... I had to give my sister my bag and be like, ‘I need you to guard this with your life, and if anything happens, interrupt what’s going on and help me.’”

-P6

For a formal situation, before this pump and CGM, I would probably just disconnect and do injections... But now that the CGM is attached with it, I feel better keeping it all connected. So I just deal with it. (about Bluetooth connectifity issues)

-P5

“I was in the middle of a quiz. It was silent. Nothing going on, and I felt it going out of insulin and I was like, “It’s at my side”. (it would look like using a cheat sheet if he peaks down) So finally, I reached down... switched it (the insulin cartridge) out and left it on the table. That way, if the professor was curious, he could see.”

-P5

While Driving / Active

“I totally do while I’m driving. Which is really dangerous! The nice thing is that the (Loop) App does have face recognition. If I put in the carbs and hit deliver, and just stick my face in front of it, it’ll go.”

-P6

Oh, I’ve memorized the functions. I bolus while driving. I will generally. Like if it says I’m high, and it’s alerting me...

-P1

“If I have someone else in the vehicle, like my brother for example. If he’s in the passenger seat, I’ll just say, “Hey, here’s my pump. Dial up a bolus of XX amount.” and he’ll just shoot the insulin.”

-P5

There have been times where I’ve had to pull over. Because I’m struggling to get it to work or because it has an occlusion alarm, and then I’ve got to respond to that, and I’ve got to resume insulin delivery.

-P7

Inconveniences

“Using the Dexcom, I’m constantly checking. But losing the riley link the other day, I started to work myself into a panic. Because I was like, “I’m gonna have to go back to my receiver, and this whole thing isn’t going to work until I find it. What if it’s giving me too high of a basal rate right now? And it’s stuck on that, because I lost the thing.” It’s anxiety inducing for sure!”

-P1

“I’m wearing it on my arm right now, and I bump into doorways. I never really thought, “ok I’m gonna hit something.” I was reading so much about people with young kids. The tube just made me nervous. I feel like I’m gonna knock that out, and I didn’t like the idea of feeling like something was constantly attached to me.”

-P7

Taking Breaks

“I don’t know what it’s like to live without half my brain going to this stuff. Like, I really don’t.”

-P1

“I started 11 years ago on a CGM, and it was the first Medtronic one. After about a year, I took a year off.”

-P1

“I’ve had issues with it. I was just at my endochrenologist on Monday, and I’ve got a prescription now for insulin pins with treciva and novolog. I’m thinking of switching to that for a time. Just to give myself a break from the pump.”

-P7

Key

discussion topic

“Tidepool user quote”

“Female respondent quote”

“Male respondent quote”

Note: All quoted Rileylink users are female

USER JOURNEY MAPS

User experience maps helped to highlight the specific difficulties people experience with insulin pumps, in their daily lives. These user experience maps were designed, based on quotes from the survey and user interviews. The maps focus on several common types of activities that participants mentioned frequently.

Each experience map is divided into four quadrants. The prompt is a given task someone would perform on their insulin pump, in order to perform a given activity. The response shows how the insulin pump acts during that activity. The last quadrant shows the reactions of users and the general public.

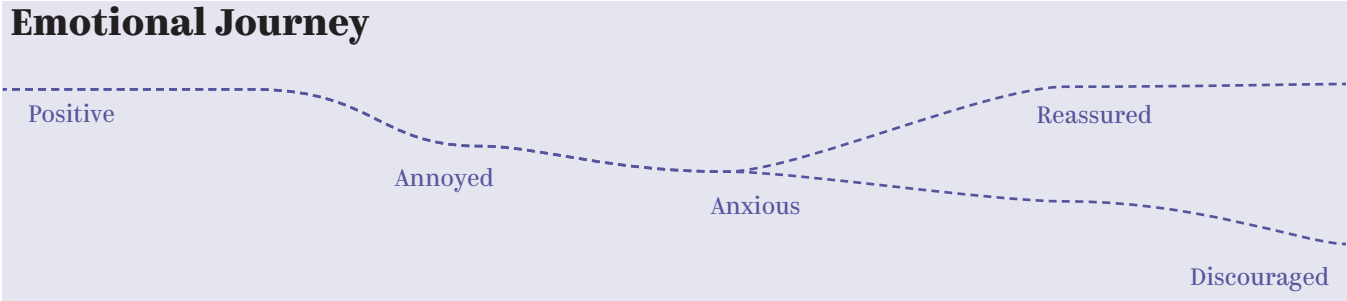
Wear-ability and alerts are two pain points that emerged from the exercise user journey.

USER JOURNEYS:
WHILE ACTIVE

The two common threads among people performing activities were that they are either distracted by devices, or the device is responsible for drawing unwanted attention.

Activities Mentioned: Exercise classes - bicycling - skiing

Prompt	Response	Reaction	Result
<ul style="list-style-type: none">• Sets a temporary basal rate.• Disconnects pump.• Proceeds without extra action.• Adjusts pump wearing location.	<ul style="list-style-type: none">• Audible Low glucose alert.• Temporary rate alert.	<ul style="list-style-type: none">• Attempts to silent pump alarm.• Feelings of being inconvenienced.• Feelings of insecurity.• Undesirable public responses.	<ul style="list-style-type: none">• Continues exercising, with a clear picture of physical condition and pump's state of activity.• Rests momentarily, to snack and allow glucose to correct.• Must stop exercising completely, to address blood sugar.



Exercising is difficult because you have to flip the pump out of the way when you do floor exercises.
-Respondent 68, Female

I was in an exercise class and the alarm went off.
-Respondent 82, Female

Clearing any alerts while skiing or wearing thick gloves.
-Respondent 66, Male

Just yesterday while riding my bike in traffic, I could hear a persistent pump alert and I was reluctant to look to see what it was and there wasn't a safe place to stop and check. I would have liked the comfort of a message sent to hearing aid - a non-critical alert, "only 15 units remaining in cartridge."
-Respondent 29, Male

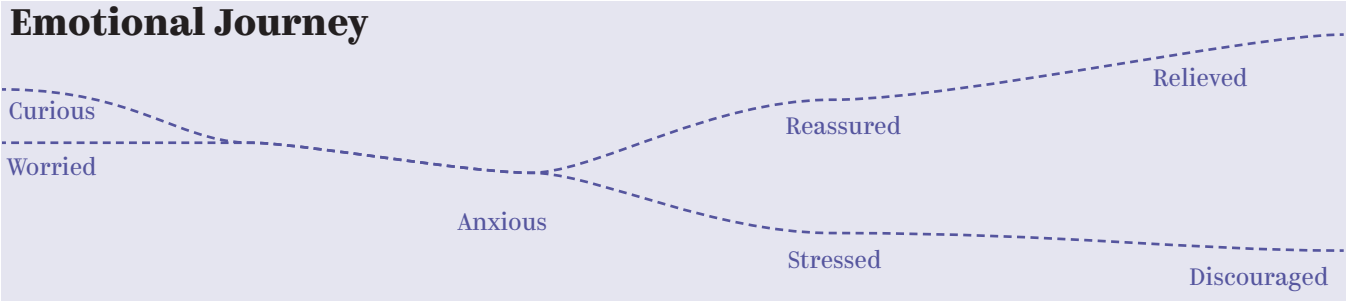
It beeped during a meditation class and I was asked to leave it in the car next time.
-Respondent 36, Female

USER JOURNEYS:
WHILE DRIVING

Whether participants use their pumps while driving or not, all contributors expressed views that using a pump while driving is not advisable and potentially dangerous.

Activities Mentioned: Highway driving - Waiting in traffic - Waiting at stop signs/lights

Prompt	Response	Reaction	Result
<ul style="list-style-type: none">Needs to check blood glucose/CGM status.Needs a meal bolus.Needs a correction bolus for high BG.Needs to correct low blood glucose.Persistent alerts won't stop until dealt with.	<ul style="list-style-type: none">Pump hasn't alarmed for an urgency.Audible high blood glucose alert.Audible low blood glucose alert.Low battery or insulin alert.	<ul style="list-style-type: none">Glances CGM data on smartwatch.Checks CGM on pump or smartphone.Feelings of being inconvenienced.Feelings of insecurity.Distraction.Attempts to silence pump alarms.	<ul style="list-style-type: none">Continues driving having quickly checked CGM data.Temporarily distracted while interacting with pump and driving.Pulls over in order to address health/pump issues.



I totally do while I'm driving, which is really dangerous! The nice thing is that the loop app does have face recognition... If I put in the carbs and hit deliver, and just stick my face in front of it, it'll bolus.
-Participant 6, Female

My girlfriend might be sitting in the passenger seat, and I'll hand her the pump and be like, "can you give me 5 units?"
-Participant 7, Male

I would just pull it out and try to take care of it at the next stoplight.
-Participant 4, Female

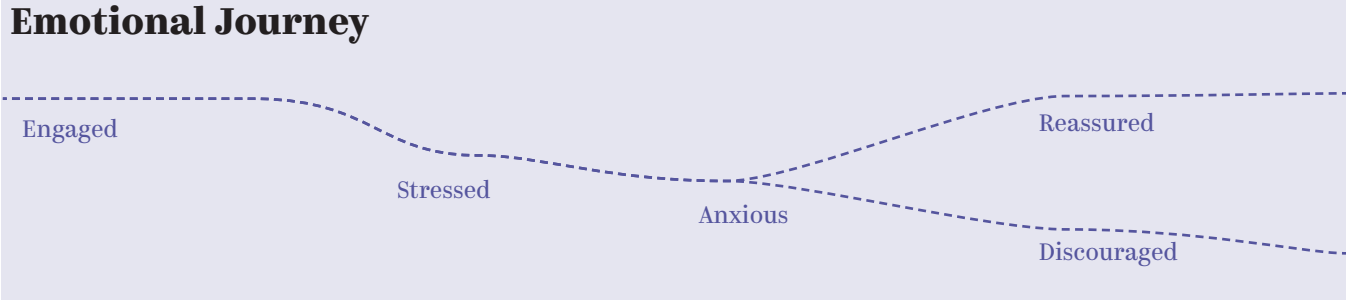
There have been times where I've had to pull over because I'm struggling to get it to work, or because it has an occlusion alarm, and then I've got to respond to that. And I've got to resume insulin delivery.
-Participant 7, Male

USER JOURNEYS:
AT FORMAL OCCASIONS

Formal occasions are another scenario where pumps and CGM's can draw unwanted attention. The formal occasion journey map also highlighted wear-ability problems for women.

Activities Mentioned: Formal dinners - Weddings - Giving lectures/presentations - Meetings

Prompt	Response	Reaction	Result
<ul style="list-style-type: none">Programming a meal bolus.Checking blood glucose.Removing the pump.Selecting different clothes.	<ul style="list-style-type: none">Audible low blood glucose alert.Low battery or insulin alert.Pump not immediately available.	<ul style="list-style-type: none">Feelings of being inconvenienced.Feelings of insecurityDistraction.Attempts to silence pump alarms.Excusing ones' self to tend to health/pump issues.	<ul style="list-style-type: none">Continues without drawing attention.Pauses to address pump/health issues with the public's knowledgeMisses out on the occasion, to address diabetes/pump issues.



I have even gone off the pump for 24 hours so I could function easily at my son's wedding.
-Respondent 87, Female

Had to wear a formal dress to a wedding. No good place to put it.
-Respondent 91, Female

As a professor, it can be awkward to stop in the middle of lecture to deal with a pump alarm. Otherwise, I generally don't worry about pulling my pump out in front of others.
-Respondent 53, Male

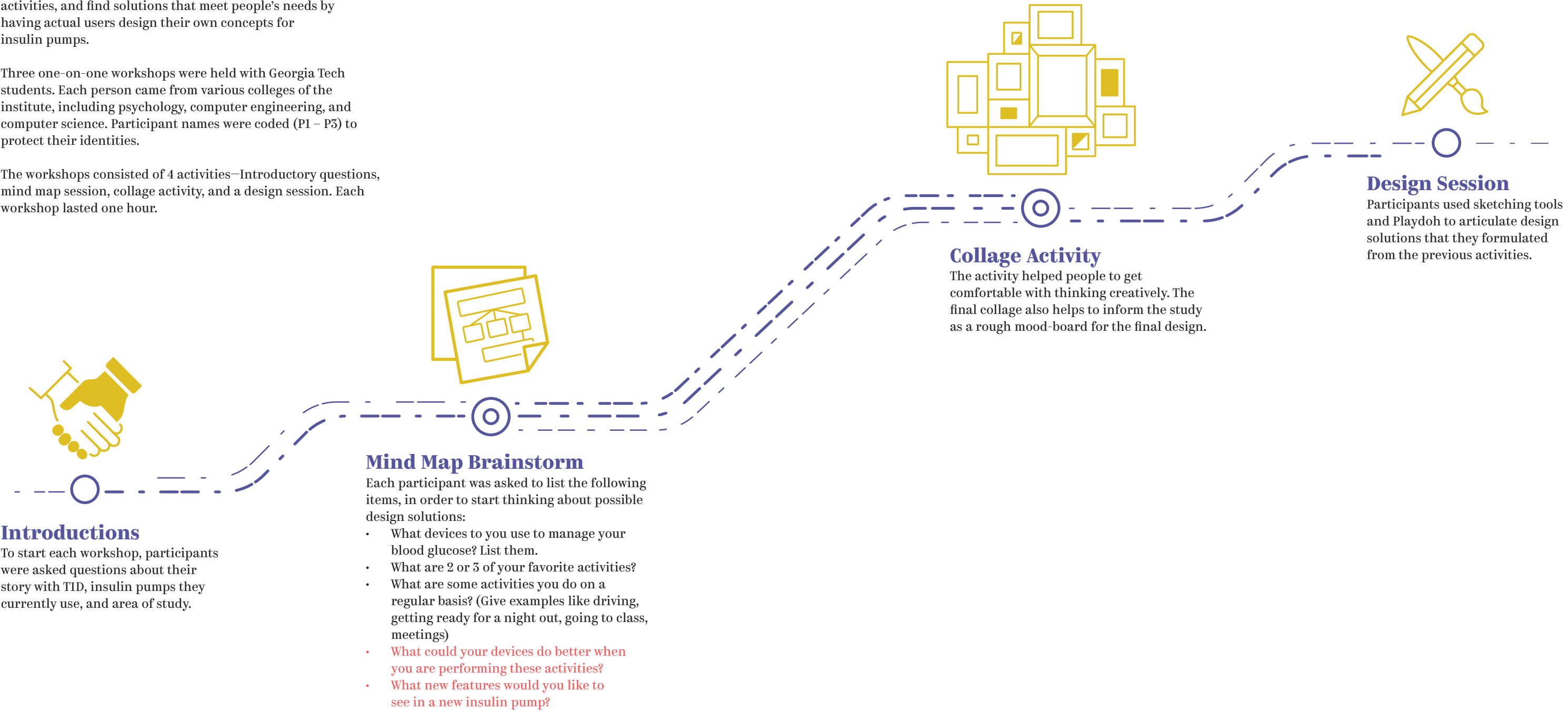
The battery needed changing during a work meeting and it alarmed every 5 minutes. I couldn't turn it off because it was under my clothes so I had to excuse myself.
-Respondent 28, Female

PARTICIPATORY DESIGN WORKSHOPS

The goal of conducting workshops was to gain better understanding of how people use pumps during regular activities, and find solutions that meet people’s needs by having actual users design their own concepts for insulin pumps.

Three one-on-one workshops were held with Georgia Tech students. Each person came from various colleges of the institute, including psychology, computer engineering, and computer science. Participant names were coded (P1 – P3) to protect their identities.

The workshops consisted of 4 activities—Introductory questions, mind map session, collage activity, and a design session. Each workshop lasted one hour.



PARTICIPATORY WORKSHOP: PARTICIPANT 1

“An ideal pump for me, would be something like an Omni, where it’s tubeless. But, I would want it to look like the Eversense. So like, the size of the eversense is ideal for me. Maybe a little bigger. Even the structure of it. More circular. Flat. I think that just looks better on the body too than what the Dexcom looks like right now. ...For me, having a smaller, flat, more ergonomically friendly pump site would be a home run.”

- Participant 1

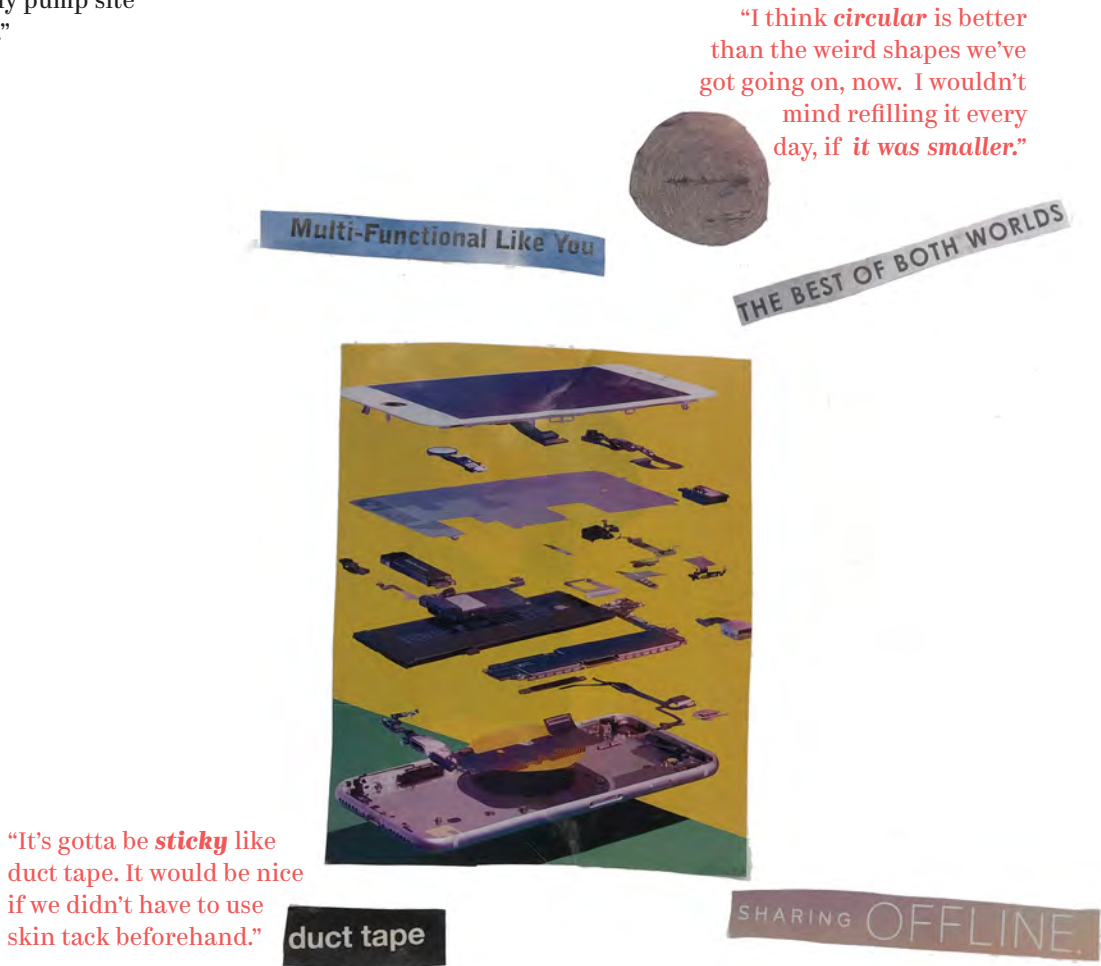
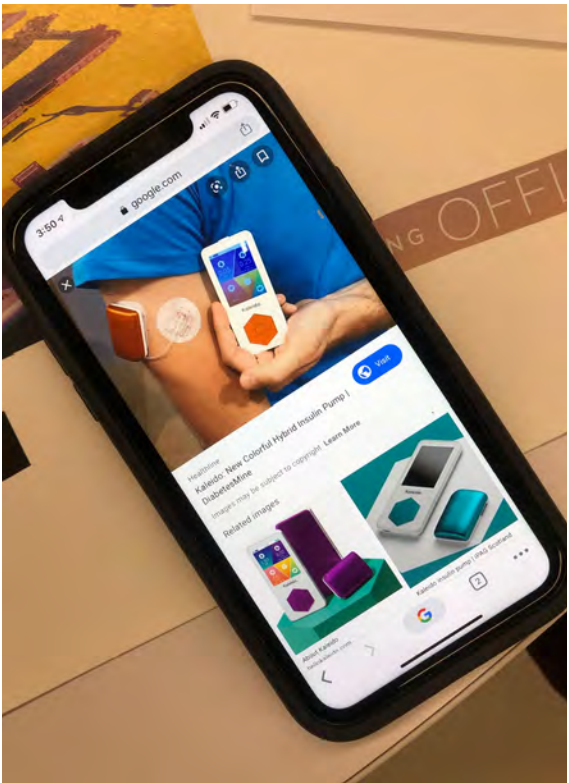
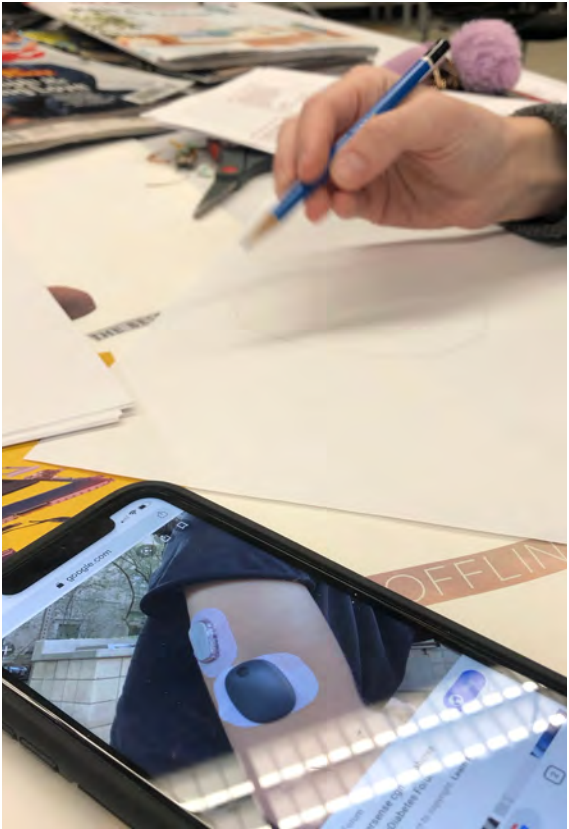


Figure 9, photograph of the collage from PD workshop 1

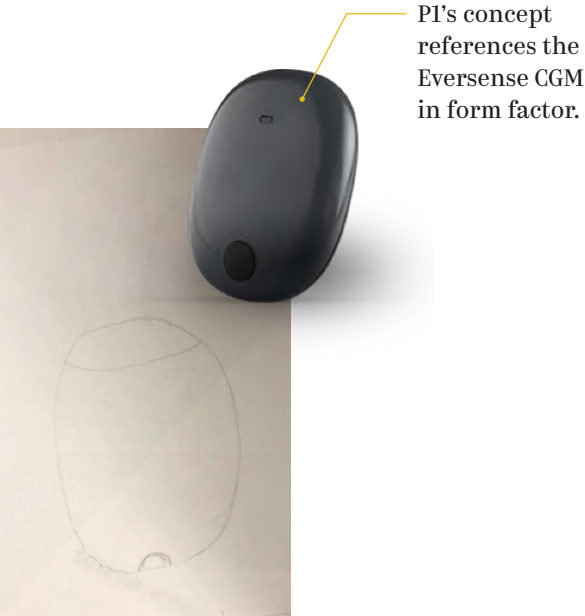


photographs taken from PD workshop 1

WORKSHOP 1 RESULTS:

Participant 1 expressed desires for an all-in-one solution, where the pump and CGM are integrated. This would reduce the number of devices one must wear, to manage diabetes.

Form was also important. P1 referenced a streamlined CGM design that resembles a pebble or smooth river rock. According to P1, doing this would make it easier for people to wear devices without seeing obvious bulges in clothing. Especially women.



How cool would it be if it was just the Insulin pump and the CGM, together!



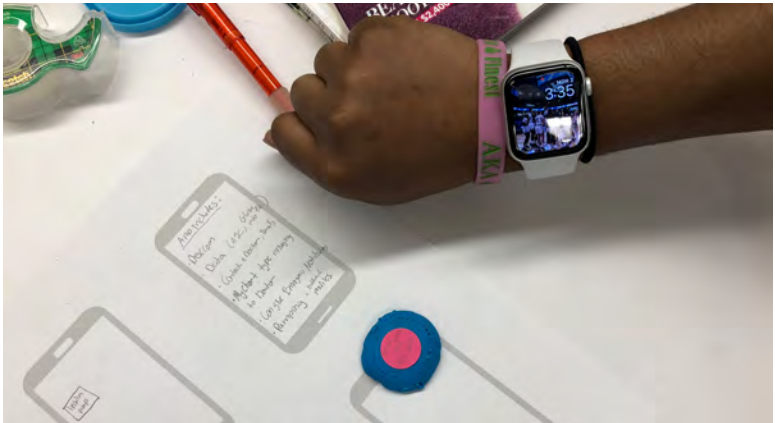
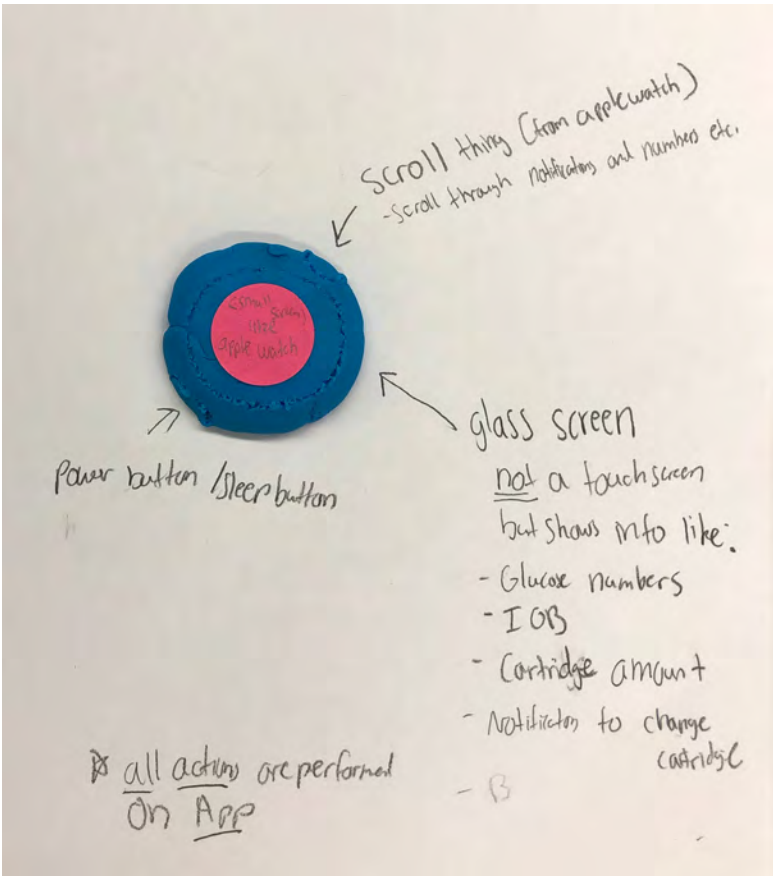
PARTICIPATORY
WORKSHOP:
PARTICIPANT 2

“Being able to be compatible with devices that we use every day. I’m always on my phone. I feel like the technology is there. We could probably just get something that could work with your phone. Just the ability to do some things on your phone, instead of just using your pump...”

- Participant 2



Figure 10, photograph of the collage from PD workshop 2



photographs taken from PD workshop 2

WORKSHOP 2 RESULTS:

Participant 2 developed a circular shaped model, that could be used as a patch-style pump or a traditional tubed pump.

During the collage activity, P1 expressed several key ideas.

- A pump that saves money by using fewer materials
- A design that does more than just deliver insulin and monitor glucose, like a Swiss army knife or multi-tool
- Integrated data sharing features that would make it easier to communicate with one's endocrinologist on a regular basis
- An aesthetically pleasing and comfortable form.

PARTICIPATORY
WORKSHOP:
PARTICIPANT 3

“It should definitely be something that’s small and out of the way. I was talking to my doctor and he was like, “you’re going to latch your wire onto a door”, and I was like, “I don’t want that to happen!”. So, it should definitely be something that’s out of the way.

For me, that interconnection has been the best. When I can see my blood sugar on my watch, that’s, like, so comfortable.”

- Participant 3



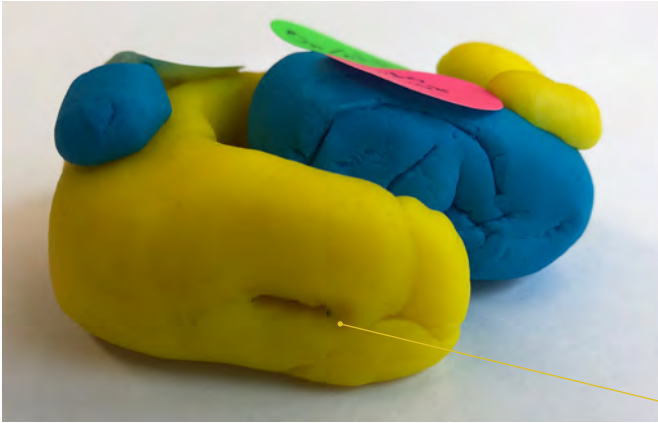
I want to be able to go out in nature, not be connected to the internet, and still be able to function properly.

It should be there when you want it to be there. Other than that, you should feel like it's not.

Figure 11, photograph of the collage from PD workshop 3



“Why not have the pump also be a CGM? If I already have two, just stick it in one. I figured it could be some sort of replaceable type pod, where you could just put it in.”



photographs taken from PD workshop 3

WORKSHOP 3 RESULTS:

Participant 3 also designed an all in one Pump/CGM. It was also important for the design to be compact. The design shows the amount of insulin in the cartridge at all times.

Other design directions that came out of this workshop included making sure the pump enables people to be active, by consolidating the pump and CGM into one device. This would reduce the number of devices to pack before leaving for a trip, or for work.

Integrating dieting tools was another key issue for P3. He felt that integrating a database of nutritional and carbohydrate information into the pump interface could reduce the stresses of memorizing carbohydrates in food.

Slot for inserting traditional glucose test strips

Showing the Pump/Pod inserted into the yellow CGM cradle.



The Pump/Pod can be removed from the cradle for convenient refilling.



PHASE III: CREATIVE DEVELOPMENT

*Assembling Design Criteria,
Benchmarking, Iterative Sketching,
CAD Models & Interactive Prototype*

ESTABLISHING DESIGN CRITERIA

Before creative development could begin, design criteria needed to be formed. Criteria was drawn from initial research findings, survey and interview insights, and the participatory design workshops. The design criteria was developed to guide the creative process to an adequate solution.

Any new design for an insulin pump must also pass FDA inspection in order to be released to the public. For this reason, FDA guidelines were also

considered so that the final design might meet the legal and safety standards of other FDA approved medical devices.

Once the strongest insights and guidelines were extracted from each stage of research, they were organized into a more concise set of guidelines which became the final design criteria. These insights were often things that reappeared in multiple stages of research.

Survey Criteria

- Pump Design**
- Remote Control Device
 - Consideration for keeping track of how much insulin is left in the pump cartridge. (Not running out of insulin at bad times)
 - Enables better wear-ability and clothing options for women
- Interactive Features**
- Better haptic/vibration feedback
 - Streamlined navigation (i.e. fewer clicks to perform certain functions)
 - Enables interaction with minimal affect on social activities

Interview Criteria

- Pump Design**
- Wear-ability options; especially when attending formal occasions like weddings.
 - Keeping track of insulin left in pump cartridge.
 - Reducing the number of devices one must carry around.
- Interactive Features**
- Enables interaction with minimal affect on social activities
 - An organized bolus history that allows the user to better understand how much active insulin is in the body.
 - Enables better interactions while performing demanding activities like driving, or job interviews.

Participatory Criteria

- Pump Design**
- All-In-One pump CGM Design
 - Option to wear as a “patch“ pump or traditional pump
 - Compact size
 - Rounded edges for more comfortable wear-ability
 - Reduce the number of devices one must carry around
- Interactive Features**
- Smartphone integration
 - Account for hacking vulnerability
 - Multi-functional

Other Considerations

FDA Regulation

The FDA has not approved any smartphone apps which could control an external insulin pump, wirelessly. Such Mobile Medical Apps could pose a risk to patient safety if they don't function as intended [13].

FINAL DESIGN CRITERIA

- Pump Design**
- Remote Control Device
 - Enables better wear-ability and clothing options, especially for women
 - Reduce the number of devices one must carry around.
 - Intentionally designed as a dedicated medical device.
- Interactive Features**
- Better haptic/vibration feedback
 - Enables interactions while performing demanding activities like driving, or job interviews.
 - Enables interaction with minimal affect on social activities
 - Smartphone integration

BENCHMARKING CURRENT PRODUCTS AND INTERFACES

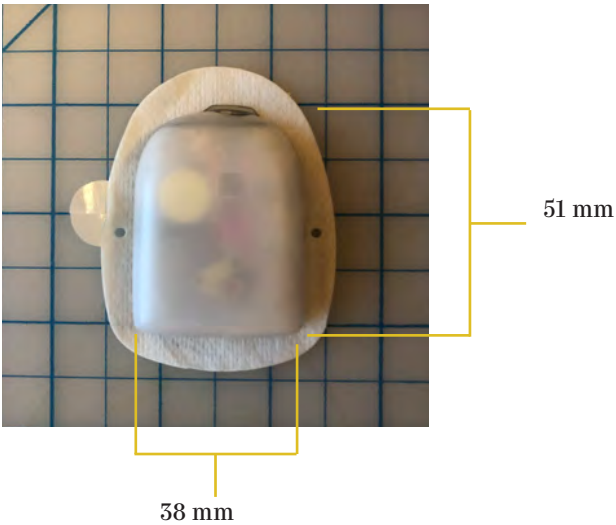
Several artifacts were benchmarked, in order to gain insight on the sizing and function of crucial internal components, and common features found in pump interfaces. This helped to establish specific standards for designing an insulin pump and interface system. Benchmarking also helped to reveal design flaws in some of the current devices and interfaces that were examined.

Once benchmarking research was done, each closed-loop system was evaluated in a product usability matrix, to help determine where the design opportunities are for a new insulin pump, in the current market.

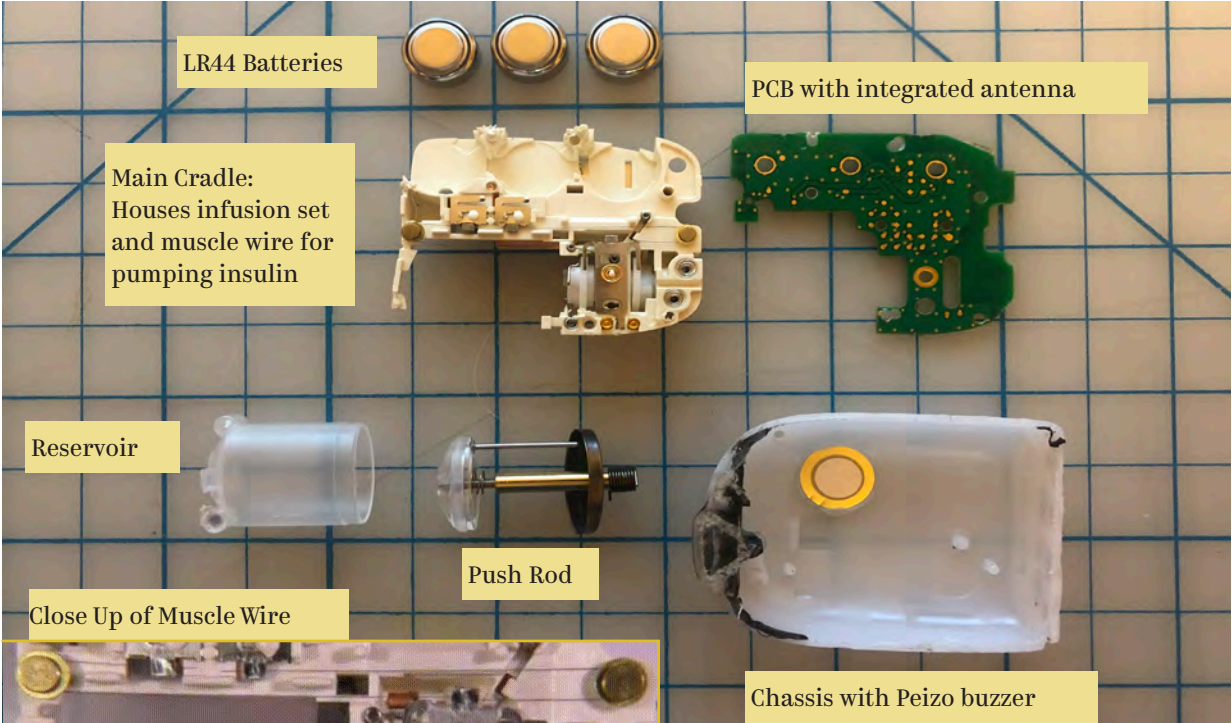
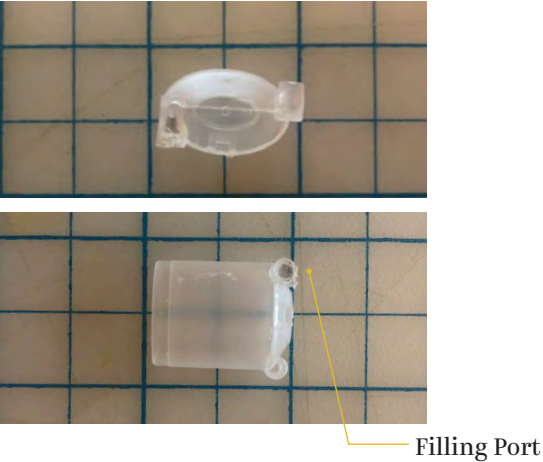
INSULIN PUMP BENCHMARKING

The patch-style Omnipod was chosen as an analog for tear-down. The pump's body measures 51mm long, 38mm wide, and 14 mm tall. While most pumps use a stepper motor for pumping insulin, the Omnipod uses a ratcheting system, powered by muscle wire. The muscle wire hardens and shortens in length when given an electrical charge, driving the gear system to rotate and pump insulin in precise increments [14]. The reservoir also has an oval profile, helping to minimize the height of the pump.

Omnipod Insulin Pump



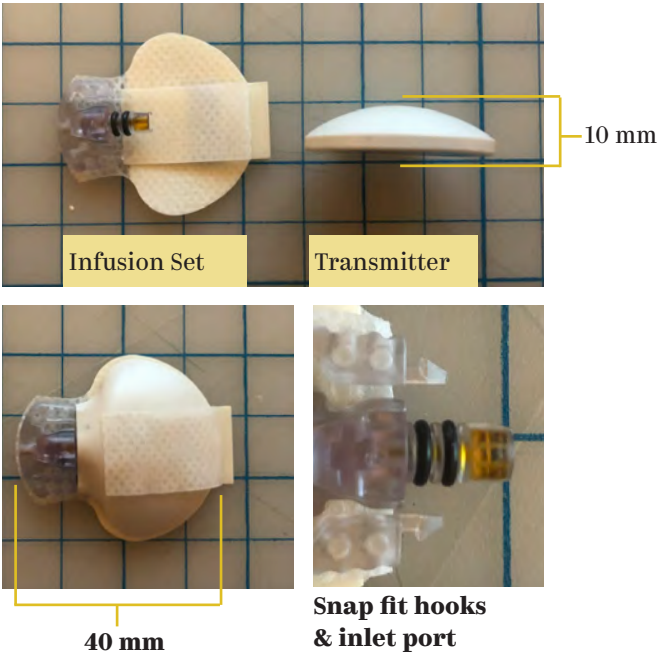
Insulin Reservoir



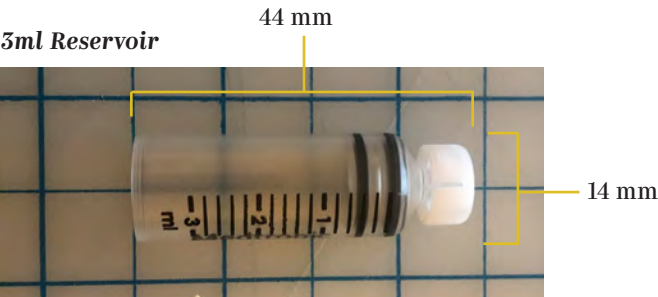
EXAMINING OTHER PRODUCTS

To help provide further reference for internal components and practical dimensions of an insulin pump, a 3ML insulin cartridge and legacy continuous glucose monitor (CGM) were examined.

Medtronic CGM



The CGM infusion set injects a small conductive wire under the skin. The transmitter attaches to the infusion set, using small snap fit hooks and gasket rings on the inlet port. The adhesive strip also helps secure the transmitter in place.



Insulin Pump Motors

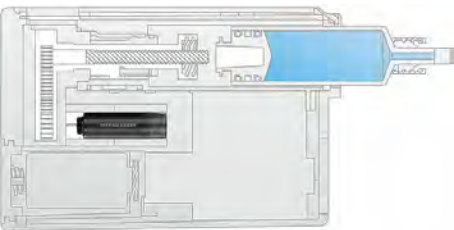


Illustration of a Faulhaber stepper motor inside an insulin pump.

Micro-motors are commonly used in insulin pumps for precise delivery. The micro-motor maker, *Faulhaber*, advertises products which are intended for use in insulin pumps. Below are examples of several motors.



DC 0816 precious metal brush motor
Length: 15.9 mm
Diameter: 8 mm



DC 0620 series DC brushless motor
Length: 20 mm
Diameter: 6 mm



AM0820 series stepper motor
Length: 13.5 mm
Diameter: 8 mm

CURRENT USER INTERFACES

Examining user interfaces of the most widely used pumps and CGM devices helped to form a benchmark for what needs to be incorporated in a closed loop system interface. The elements found in nearly all of these UI include the following:

- CGM glucose levels
- Active insulin in body
- Insulin in the pump
- Current time
- A trend graph



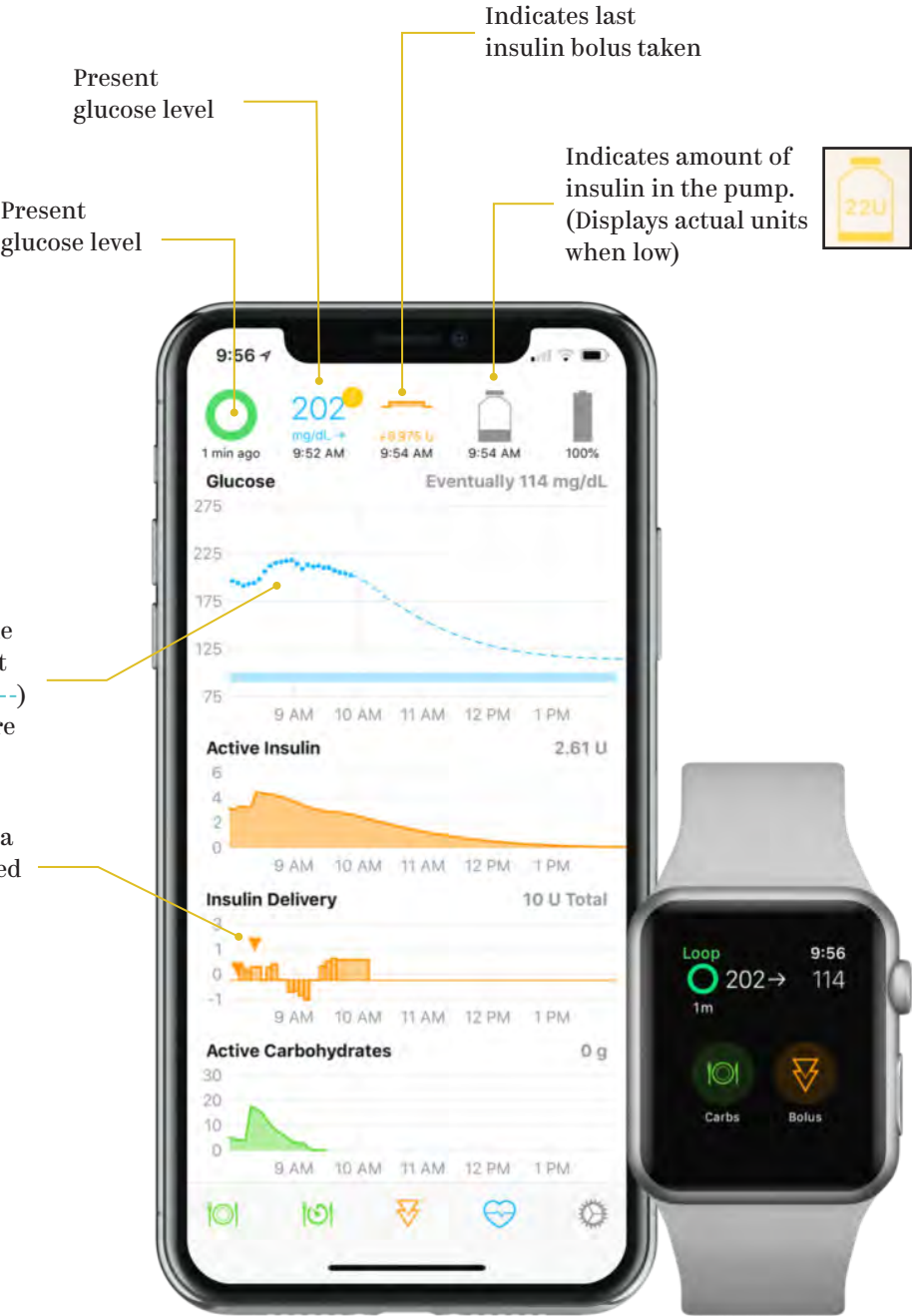
TIDEPOOL LOOP

Tidepool loop is the only mobile app that can be used to control an insulin pump. Since the FDA has not approved apps for the purposes of controlling pumps, people with T1D must use this open-source technology at their own risk.

Loop is a very comprehensive app, accounting for extra factors like exercise patterns, and food fat content in order to deliver more precise increments of insulin over time.

Glucose Trends graph: the dotted line indicates past levels. The dashed line (---) indicates predicted future glucose levels.

Triangles indicate when a bolus has been programmed by the user.



LOOP APPLE WATCH USER FLOW

Bolusing user flows are nearly identical between smartphone and watch. The smartphone flow does take an extra step, by requiring finger print or facial scan authentication before delivering a bolus.

CGM Data displays as a complication on the watch face.
Touching the complication opens the app.

Tap "Carbs" to initiate a meal bolus.

Tap "Bolus" to initiate a correction bolus.

Use the + or - icons (or rotate the watch crown) to adjust units of insulin.
Selecting different food icons will deliver insulin over extended time periods, according to food's absorption rate.

Press "Bolus" button.

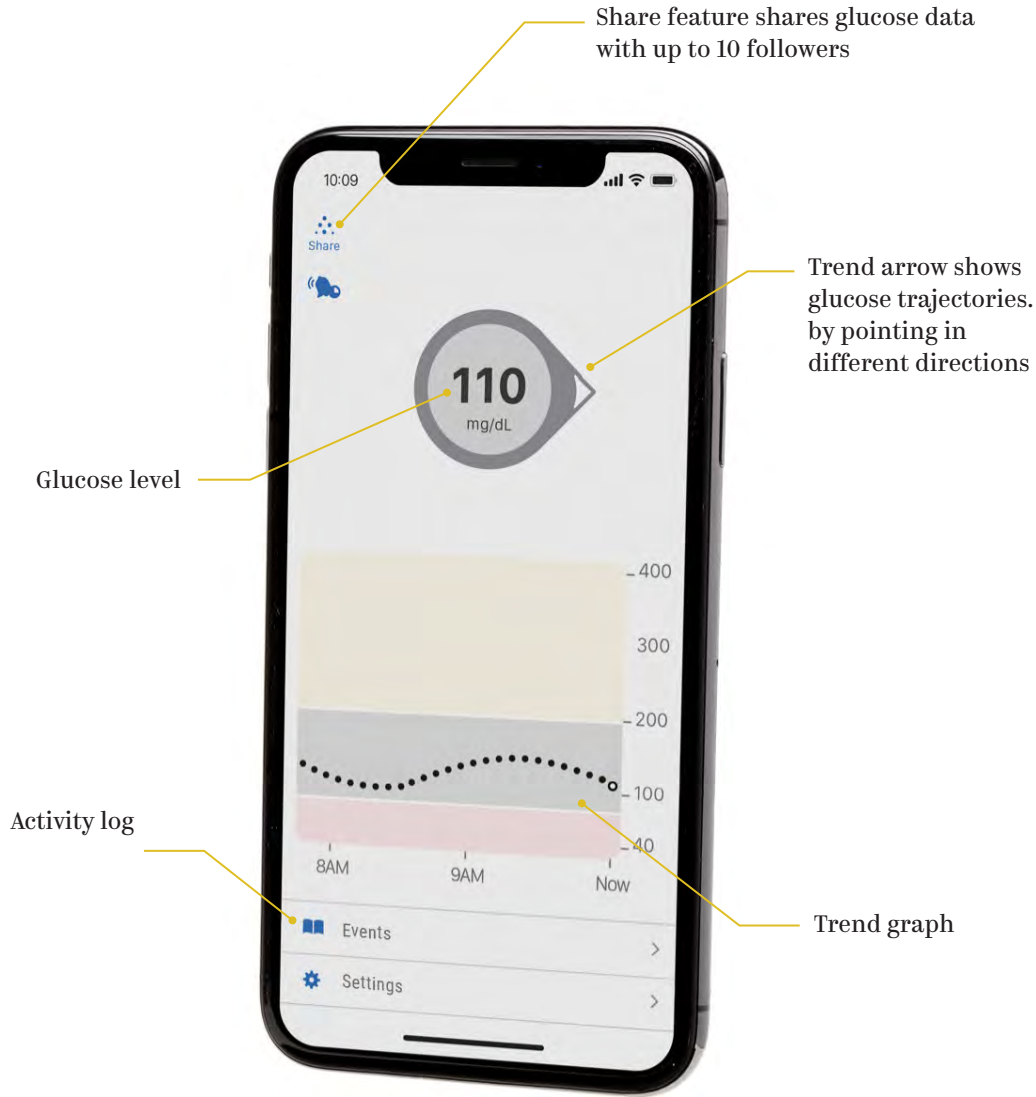
Insulin pump automatically delivers specified insulin.

Photographs taken from:
<https://www.youtube.com/watch?v=V5Tqh6b51zU>

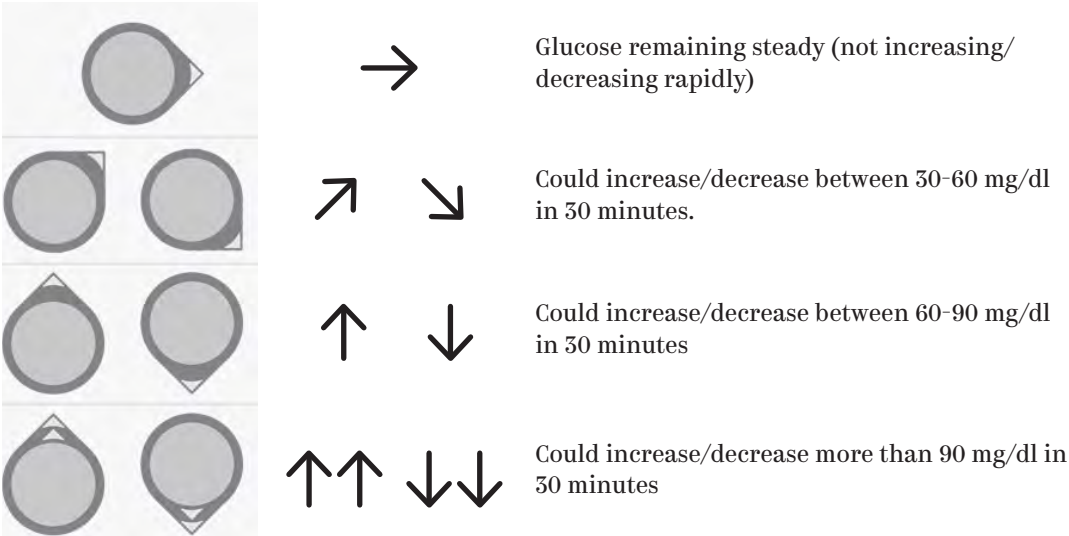
DEXCOM
APP

The dexcom app works with the company's continuous glucose monitors, to display blood glucose data.

The app displays one screen, showing glucose data. Users cannot use the app to perform functions.



Trend Arrow Functionality



Dexcom Apple Watch Layout



DEXCOM APPLE
WATCH APP

The Dexcom watch app utilizes one screen, showing a trends graph as well as the user's current glucose. The arrow icons next to the glucose number indicate glucose trajectory (whether blood glucose is going up or down).

CGM data from the dexcom app can also be displayed as a complication on several main watch face layouts of the apple watch. This allows users to check CGM data without needing to drill further into the apple watch's menus.

CGM Data Shown as a Complication on the Watch Face



OMNIPOD DASH CONTROLLER

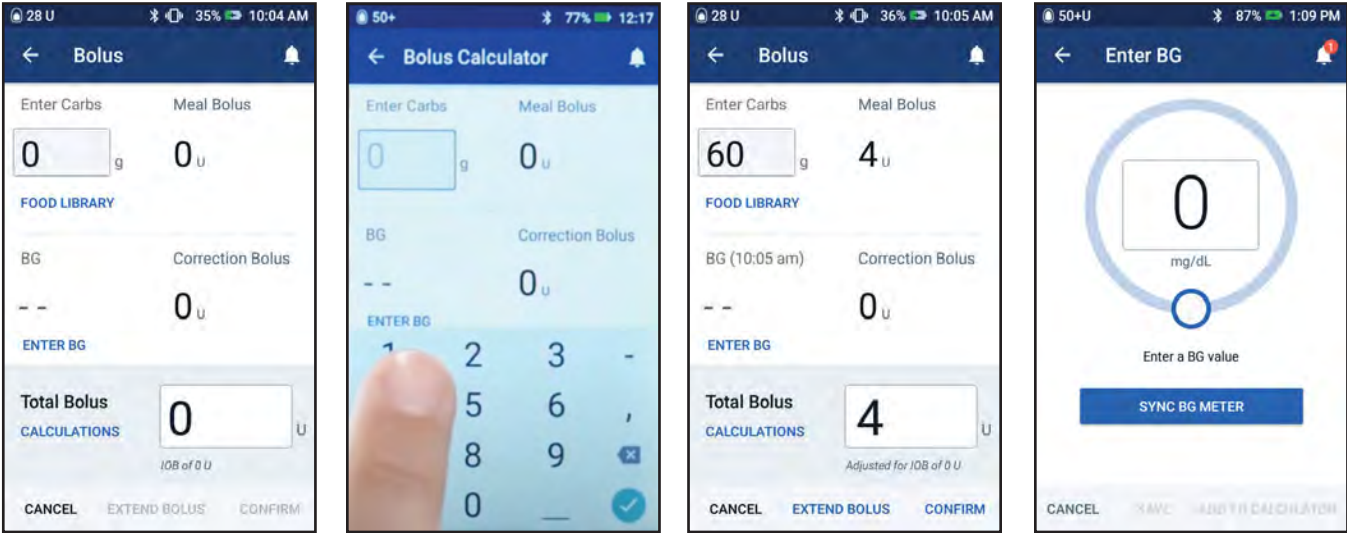
The Omnipod Dash system uses a cellular-disabled Samsung Galaxy as the controller. This is the only system that uses a wireless controller as the primary means to control the insulin pump.

This system does have a few limitations. It does not integrate with a CGM device. While the wireless controller is an actual smartphone, the device doesn't allow users to download apps.

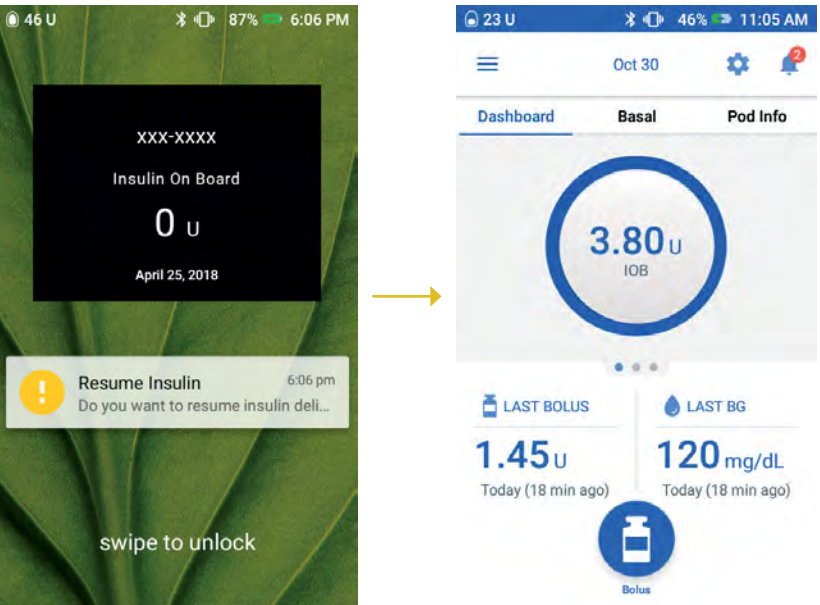
The application has a few usability issues. There isn't a uniform process for number entry. In the bolus section, the user types the number of carbs, but uses a slider to enter a blood glucose number. The bolus section also jumps to a separate page to allow the user to enter a glucose number.



OMNIPOD DASH BOLUS USER FLOW



- 1). Tapping the bolus button brings the device to the bolus section.
- 2). Tapping the “carbs“ text box allows carbohydrates to be typed in.
- 3). Tap the dashes (- -) in the BG section to enter blood glucose, manually.
- 4). A new screen appears for entering blood glucose.

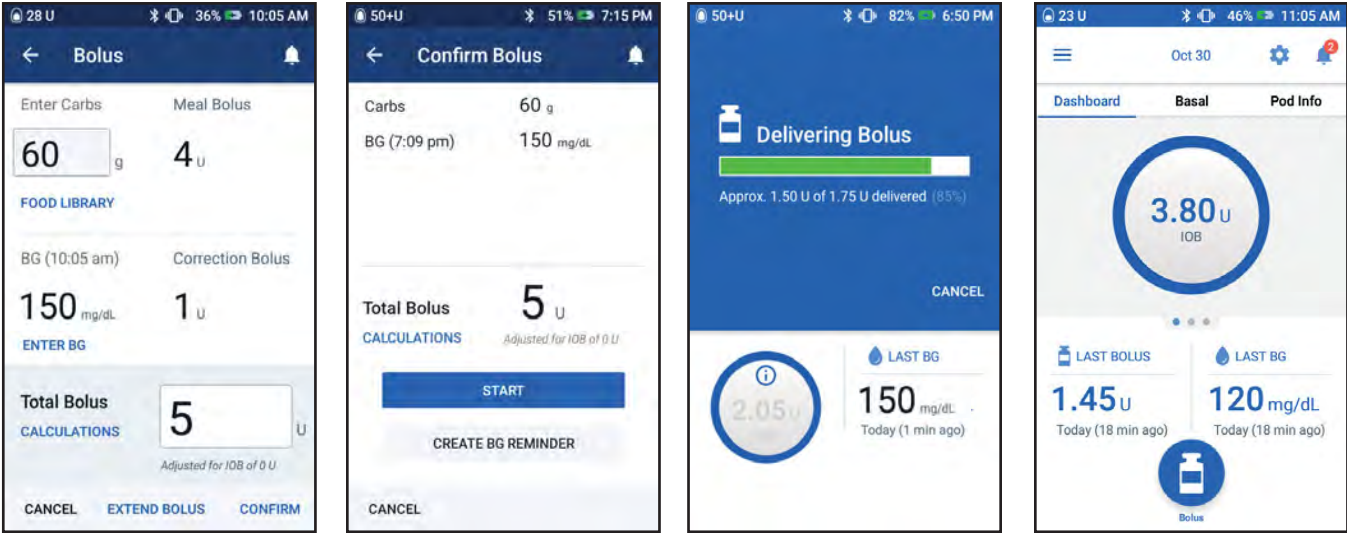


Lock Screen

Home Screen

The controller uses a lock screen that resembles most smartphone lock screens. Users can set the device to require a pass code.

The first screen that appears after unlocking the device is the Omnipod home screen.



- 5). The calculator jumps back to the bolus screen after a glucose has been entered.
- 6). Review the confirmation screen before starting a bolus.
- 7). A bolus progress screen appears, after the bolus has been started.
- 8). The interface returns to the home screen after the bolus is complete.

Tap “CONFIRM“ to go to the next screen.

EXISTING PRODUCTS

USABILITY MATRIX

Five common Pump/CGM systems were assessed for wear-ability and interaction. Systems with fewer required devices score higher for wear-ability, since there's less to carry. Systems with multiple available interface options scored a higher interactivity rating. Devices that offer discreet operation include smartphones and smart watches, which do not resemble medical devices. Tubeless design scored higher for wear-ability, since participants and survey respondents frequently commented on tubing catching on objects. Wireless control helps with wear-ability and interaction, because women often choose these devices in order to have better clothing options.

	Minimum required devices	Potential number of devices to carry	Available interface devices <i>Red text signifies input/controller device</i>	Tubeless Design	Interface options with discreet operation.	Offers Wireless Control
Tandem T: Slim + Dexcom CGM	2	4	<ul style="list-style-type: none">Pump interfaceSmartphone appSmartwatch app	No		No
Omnipod + dexcom CGM	3	5	<ul style="list-style-type: none">Wireless controllerDummy smartphoneSmartphone appSmartwatch app	Yes	<ul style="list-style-type: none">Dummy Smartphone	Yes
Medtronic 670G + Proprietary CGM	2	3	<ul style="list-style-type: none">Pump interfaceSmartphone app	No		No
RileyLink + Legacy Pump + Dexcom CGM	3	5	<ul style="list-style-type: none">Smartphone appSmartwatch appPump Interface	No	<ul style="list-style-type: none">SmartphoneSmartwatch	Yes
RileyLink + Omnipod + Dexcom CGM	3	6	<ul style="list-style-type: none">Wireless ControllerSmartphone appSmartwatch app (Dummy smartphone not available for omnipod + rileyLink)	Yes	<ul style="list-style-type: none">SmartphoneSmartwatch	Yes



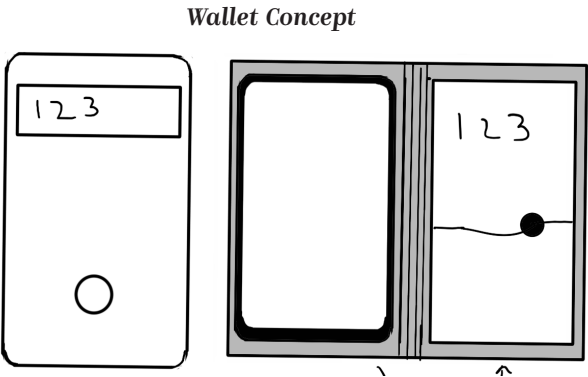
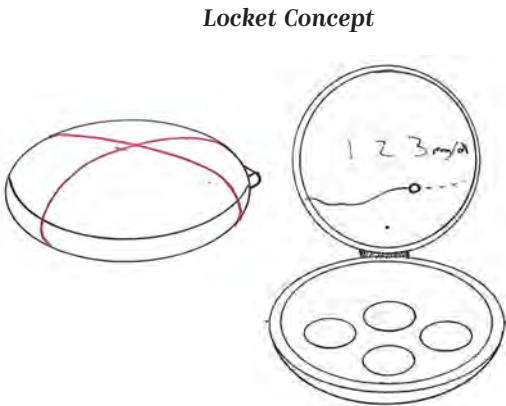
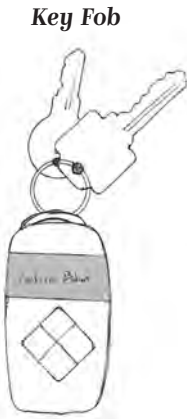
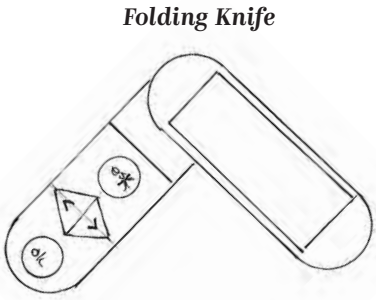
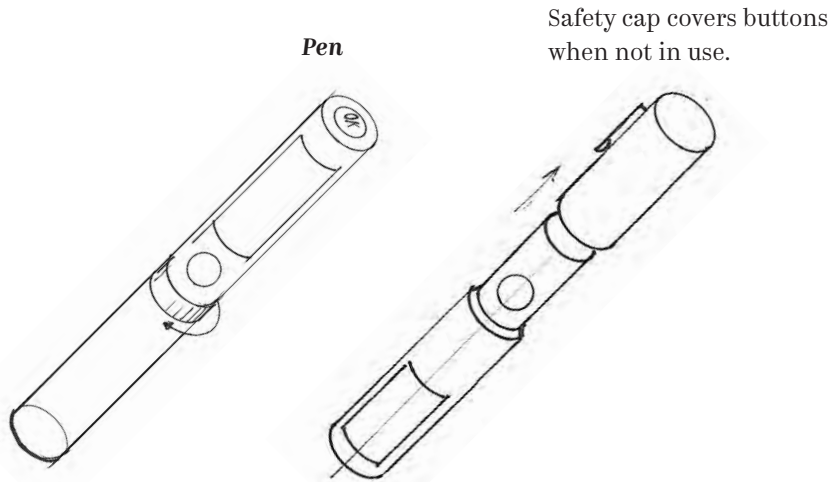
ITERATIVE SKETCHING

Sketching allowed for fast iterative idea generation, based on the design criteria. The processes for sketching the physical pump, controller, and digital interface were very similar. At the beginning of the process, a myriad of rough sketches were produced. Over several internal reviews with my committee, those ideas were narrowed down until a final cohesive concept was formed.

EARLY CONTROLLER SKETCHES

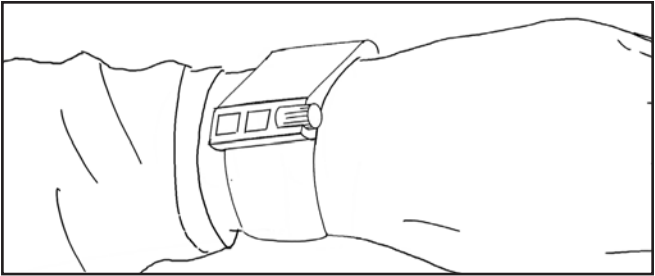
Several forms were considered for a new controller. It was important that the device fit the form of objects that people carry on a daily basis. Smartphones, wallets, keys, jewelry, multi-tools, and pens often fit that description. After several sketches, the concept for a wrist-watch controller quickly emerged as an ideal form, due to the familiarity and benefits of a smartwatch-style controller.

- Key Benefits**
- Ideal body placement for haptic feedback
 - Discreet interaction
 - No need for cellular capabilities (unlike smartphones and mobile medical apps which could pose risks)

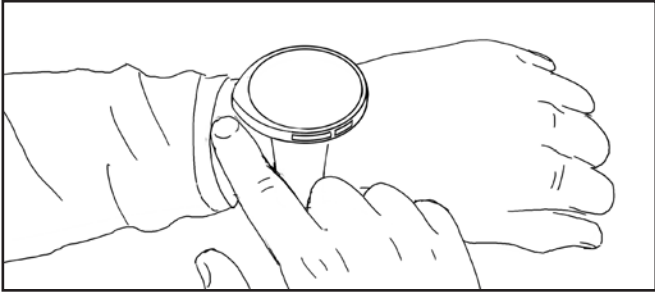


INITIAL WRIST CONTROLLER CONCEPTS

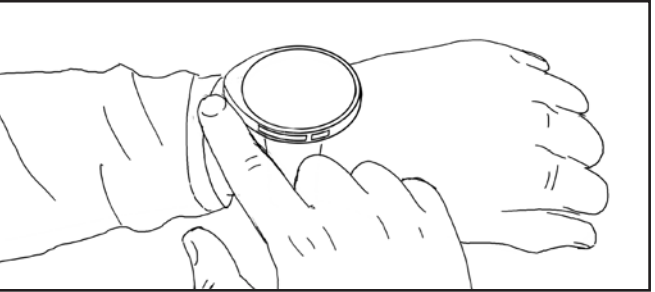
Combination of buttons and 1 dial



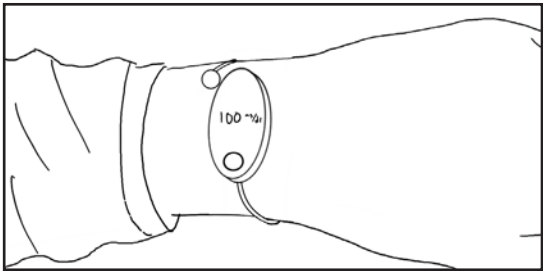
droplet



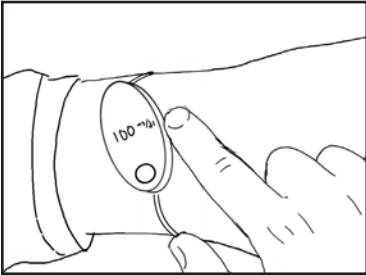
Droplet: tilt the face to scroll content.



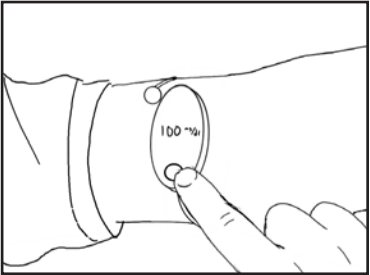
Leaf



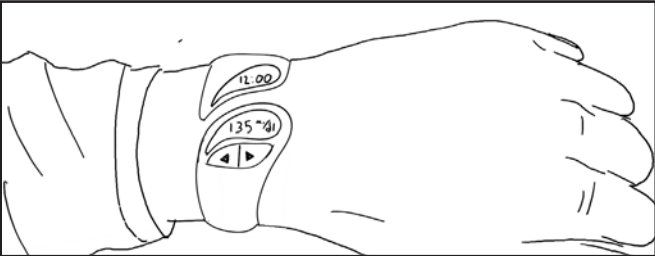
Tilt the leaf face to scroll



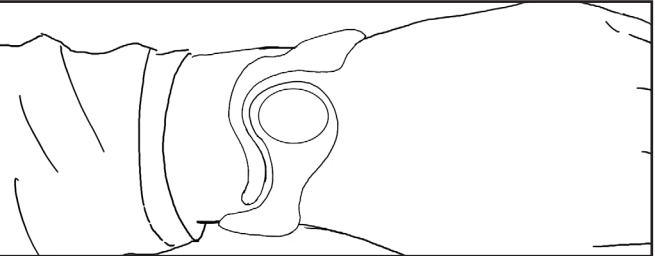
Press the button to select / advance screens



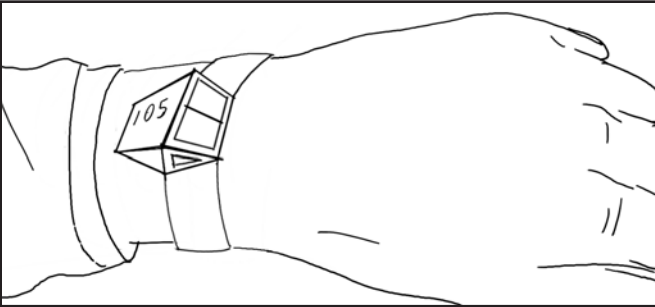
Ying Yang



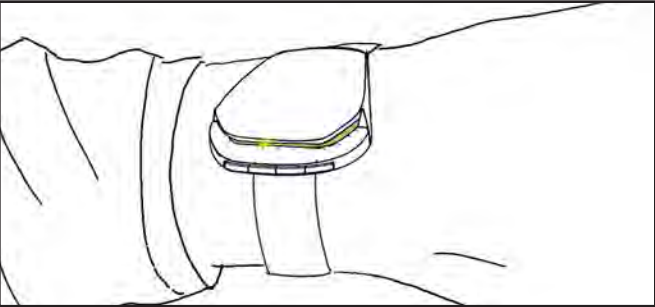
Blobular



Hexagon



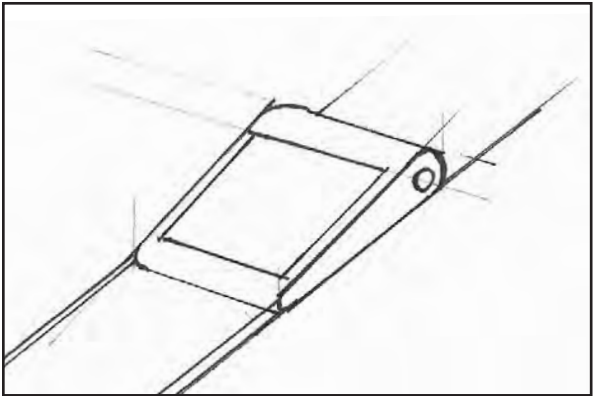
Robo face



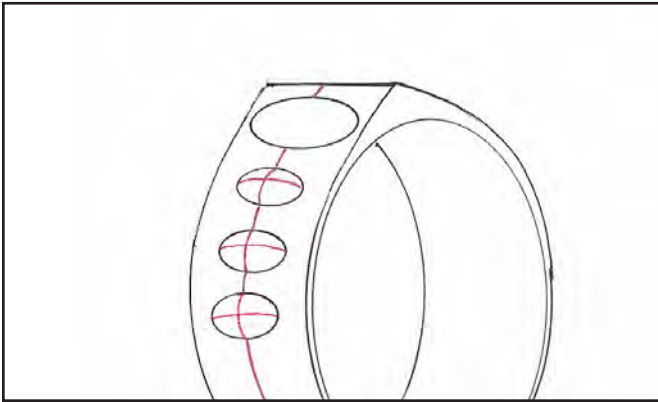
SKETCHING: WRIST CONTROLLERS

The watch controller went through several concept sketches before settling on a final design. Goals for determining a form were to incorporate a non-touch screen interface, which may facilitate effective “eyes-free“ interaction. The form and visual style of the controller also needed to pair with the pump design as part of a product family.

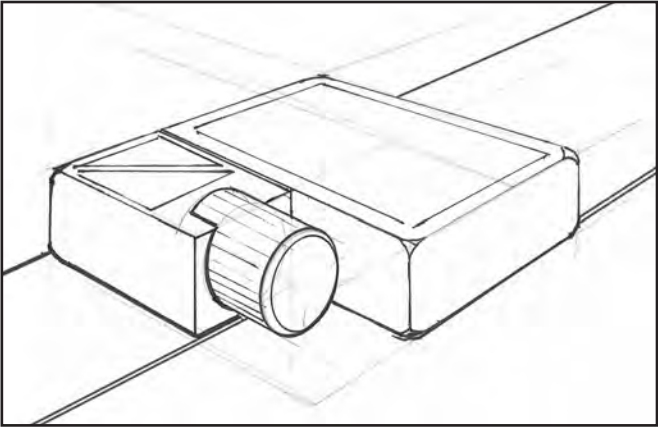
Wedge



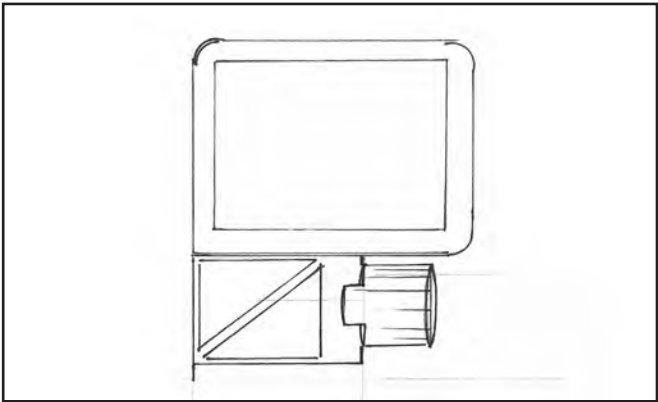
Round Face. Hump Buttons



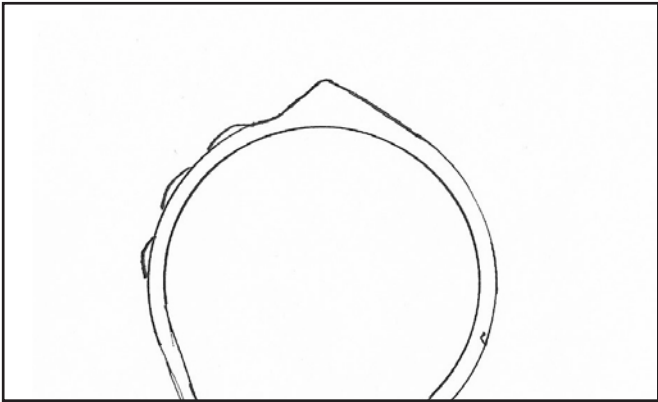
Rams Concept



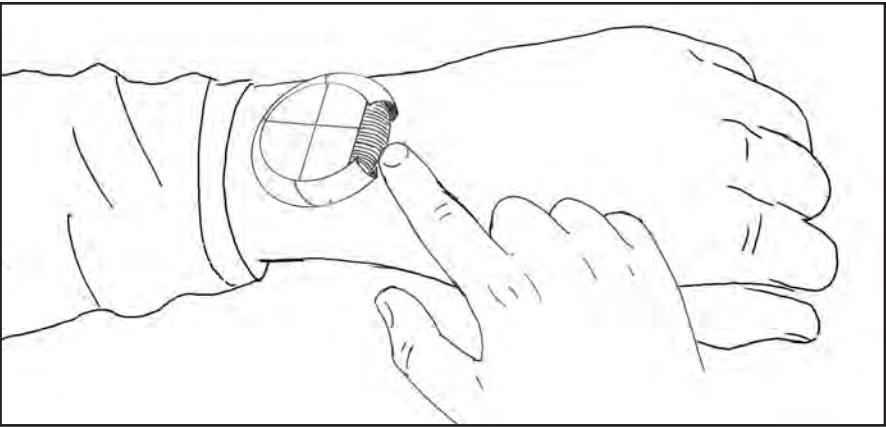
Rams: Top View



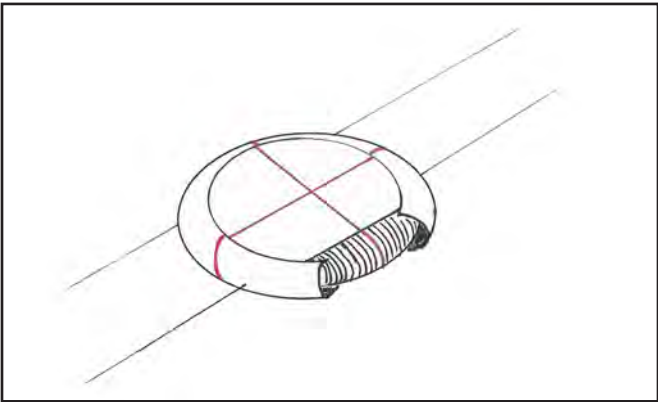
Round Face. Side View



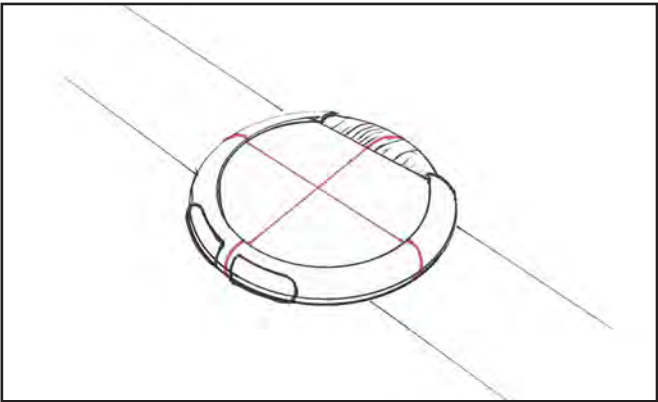
Circle Exposed (exposed side is used for swiping / scrolling content)



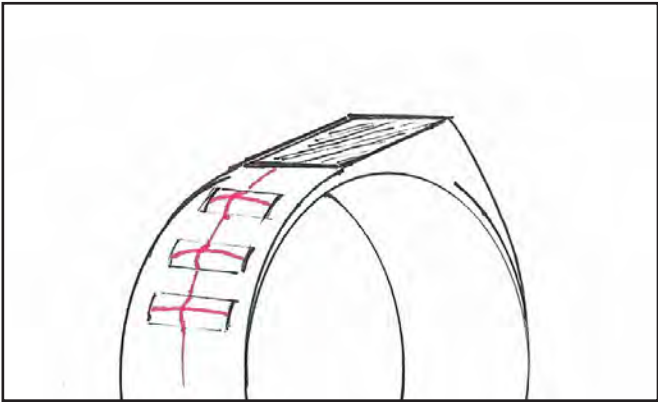
Circle Exposed: Front View



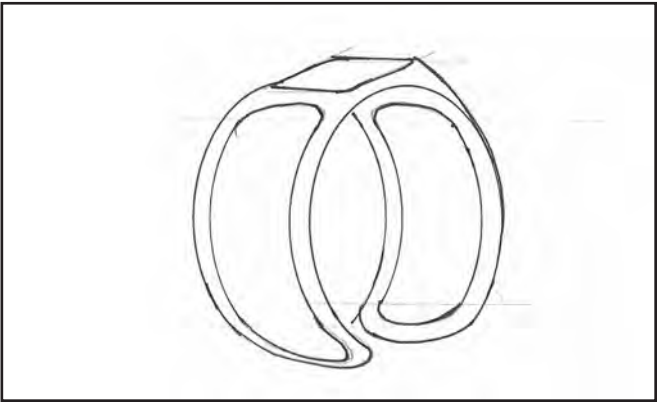
Circle Exposed: Back View



Square Face. Hump Buttons.



Breathable Band



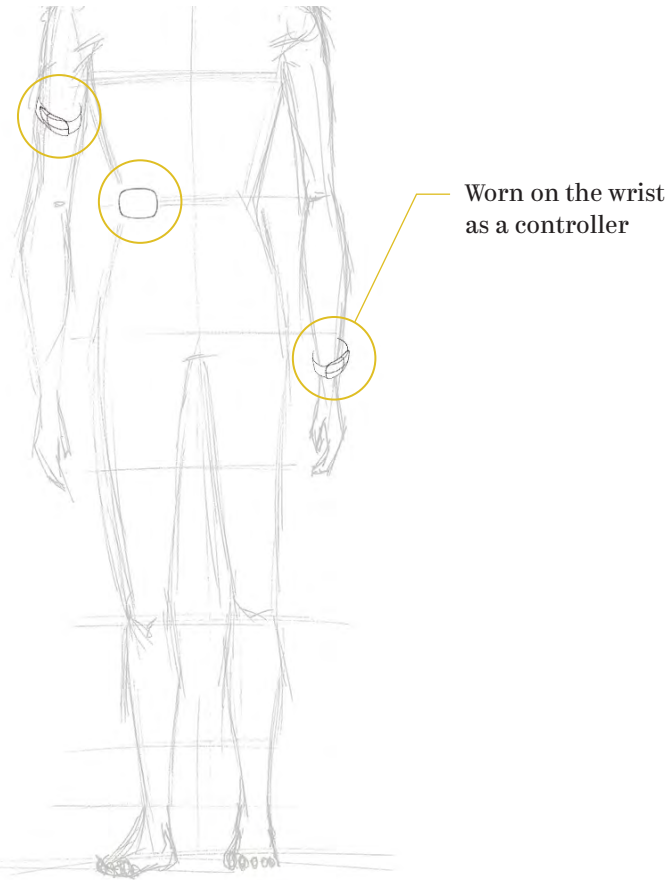
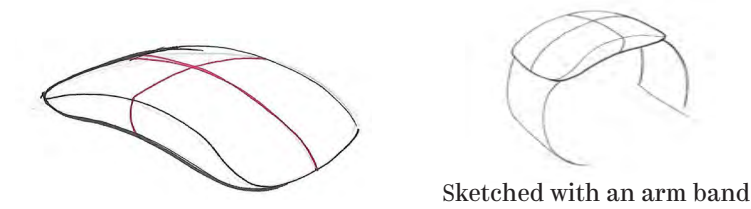
SKETCHING: PUMP FORMS

The patch style pump was chosen as the form to fulfill design criteria. Patch style pumps tend to offer more flexible clothing options for women, since they are placed directly on the body, and not in a pocket, belt-clip, or carrying case. As survey and interview participants mentioned, patch pumps don't have any tubing to catch on objects. Lastly, all of the pump designs from the participatory sessions were based on patch-style pumps.

Curved Plinth Shape:

Intended to fit around the curvature of the body/wearing locations.

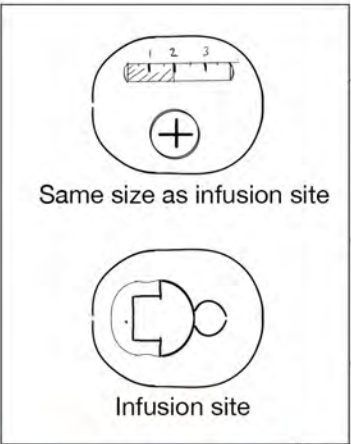
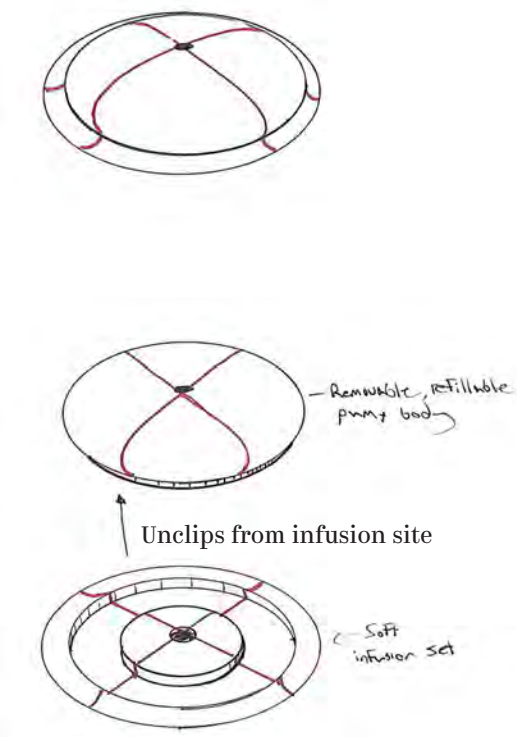
- Form design may also work for a controller



Refillable Patch Pump Concept:



Miniature pump design:
For use while exercising, or as an emergency backup.

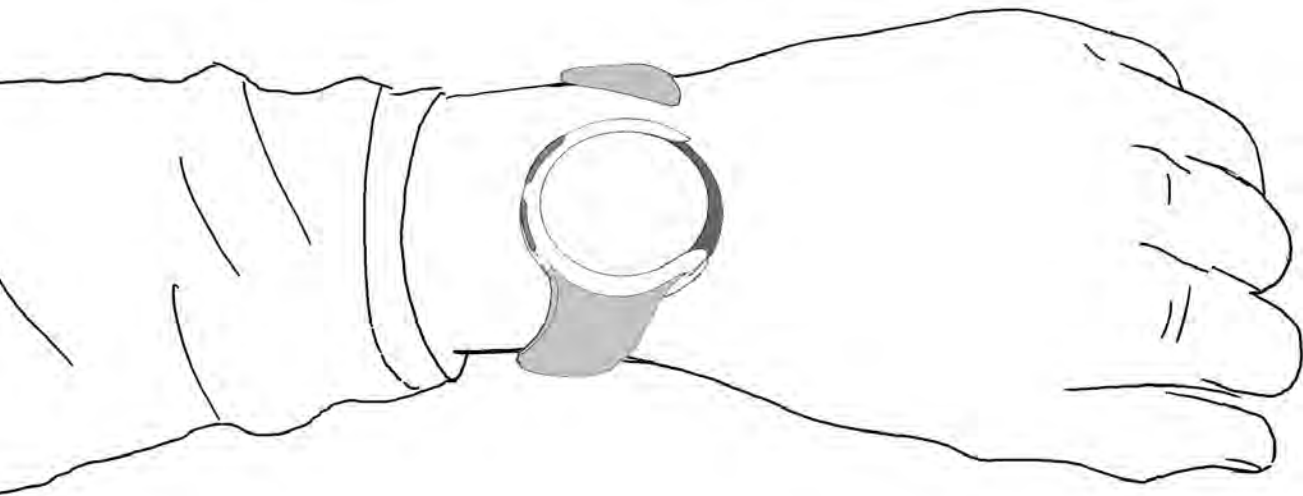


FINAL SKETCHES:
WRIST CONTROLLER

The circle concept was chosen for the watch controller. The controller features a capacitive touch sensor pad, for swiping through screens. There are two buttons; one selection button and one back button. The detail sketches also account for the crucial internal components for the controller.

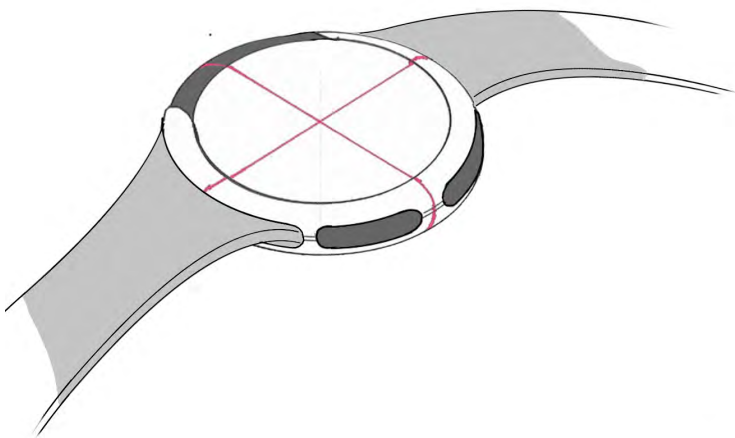
Option 1: Modern Band

Wrist View



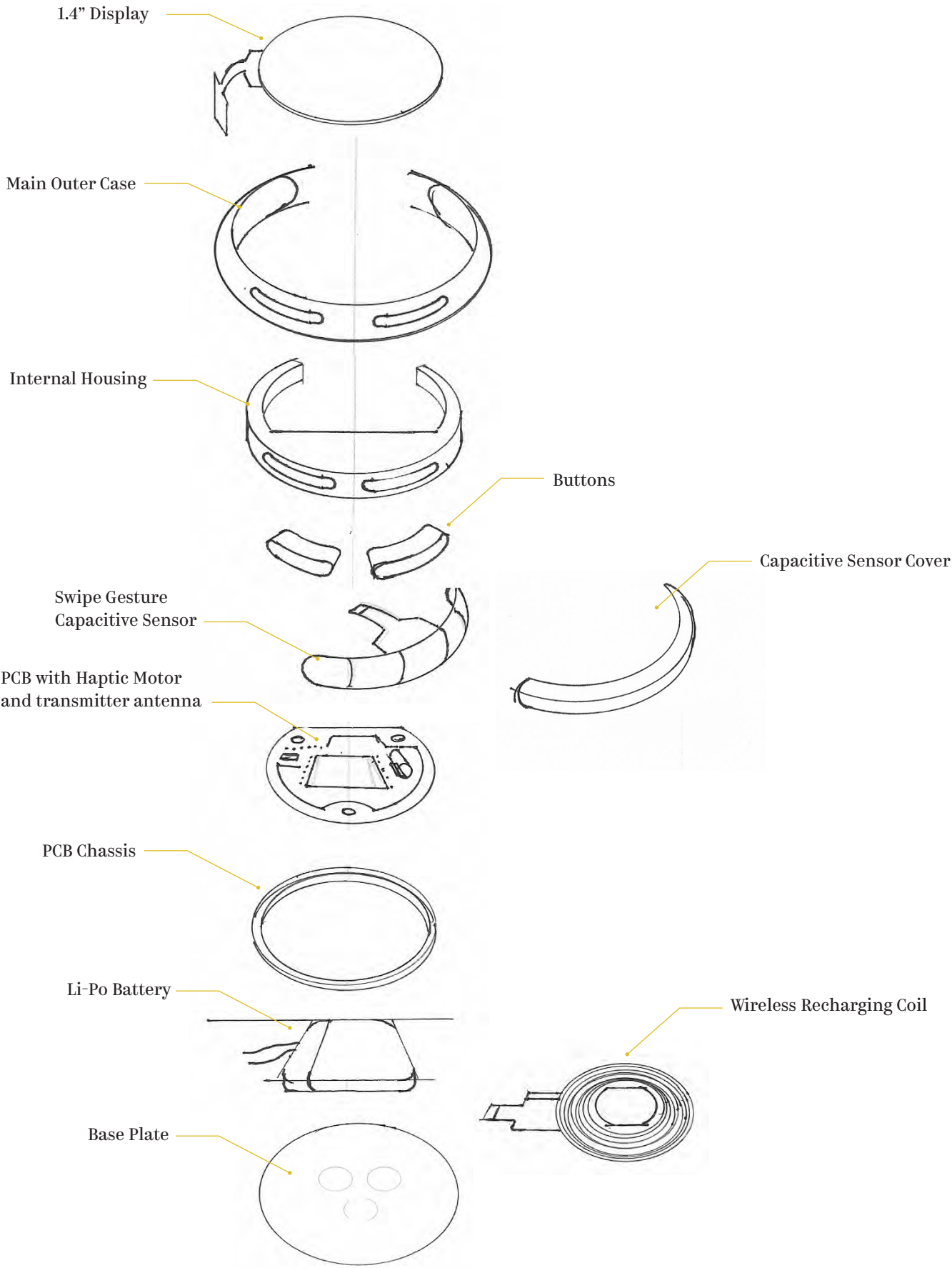
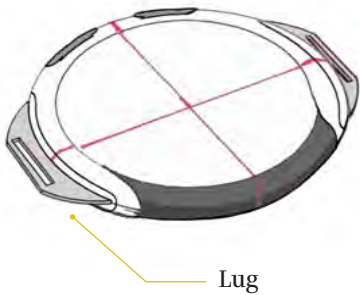
Option 2: Band integrated into case:

Button View



Option 3: Waterjet/Stamped Lug

Swipe Pad View

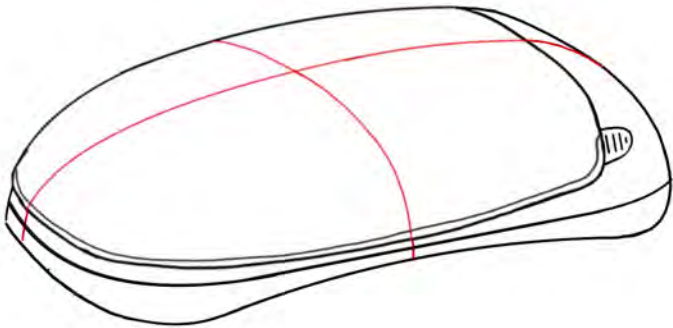


FINAL SKETCHES: INSULIN PUMP DESIGN

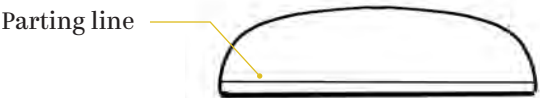
The final patch-style pump design consists of a holster which houses the infusion set for insulin delivery and CGM sub-cutaneous probe. The Pump Body slides onto the holster and is fastened into place with snap-fit hooks.

Two main differentiators of this concept are that the holster/body design allows the user to refill the pump without changing pump sites on the body. The second is the curved profile, which is meant to fit more closely to the body.

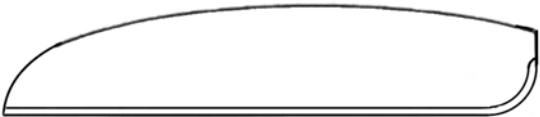
Pump and CGM Holster



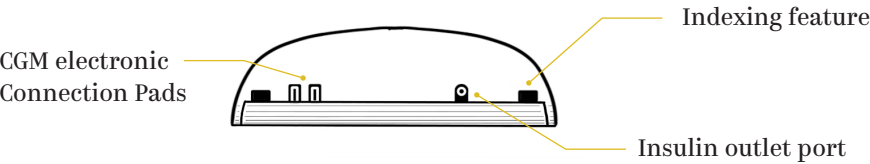
Pump Body: Front View



Pump Body: Side View



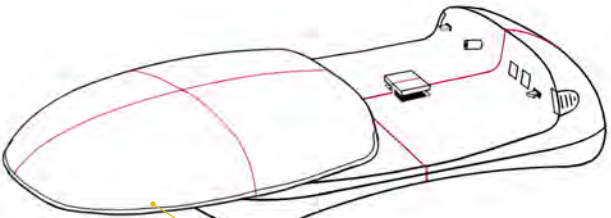
Pump Body: Back View



Pump and CGM Holster: Top View



Pump body slides onto CGM Holster and fastens to snap-fit hooks.

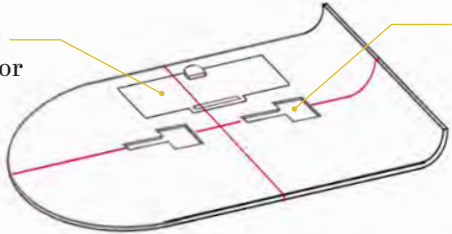


Side View



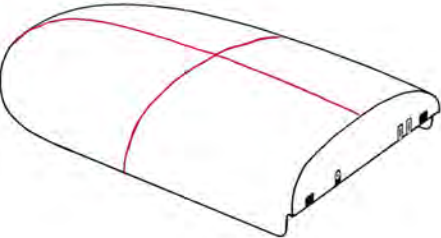
Lower Half of Pump Body:

Reservoir access door



Keyholes fit over slide-fit tabs

Upper Half of Pump Body:



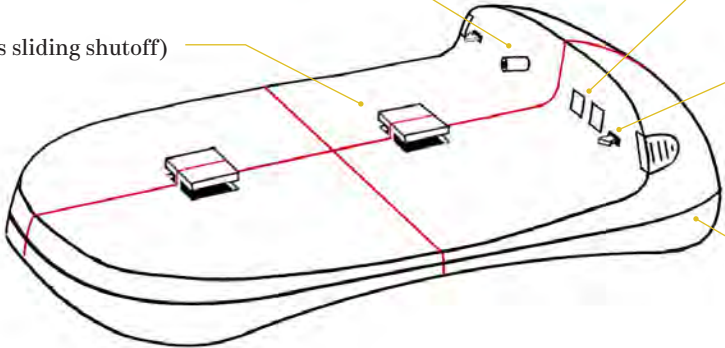
CGM Holster

Slide-fit tabs (injection mold requires sliding shutoff)

Insulin outlet port

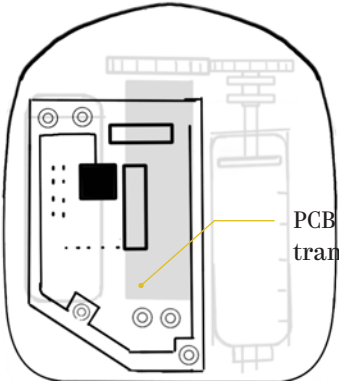
CGM Connection Pads

Snap-fit Hooks



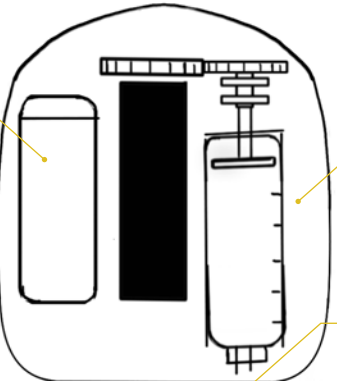
Parting line

Pump Body: Internal Parts



Li-Po battery

PCB with transmitter antenna



Reservoir

Outlet Port

EARLY
UI SKETCHES

All UI Sketching was done within a 1.4" circle, so that accurate scale is taken into account.

Each home screen sketch shows 2-3 pieces of information at a time; Current time, a graphic representation of CGM glucose readings, and the amount of insulin left in the pump.

Initial Sketches

Only showing glucose

Only showing glucose

Analog clock graphic.
Glucose shown as 106.

Showing time and battery.

Divider line moves up and down, with glucose reading

Showing time, glucose (82), and units in pump (185 u.)

Navigation Layout Exploration

home

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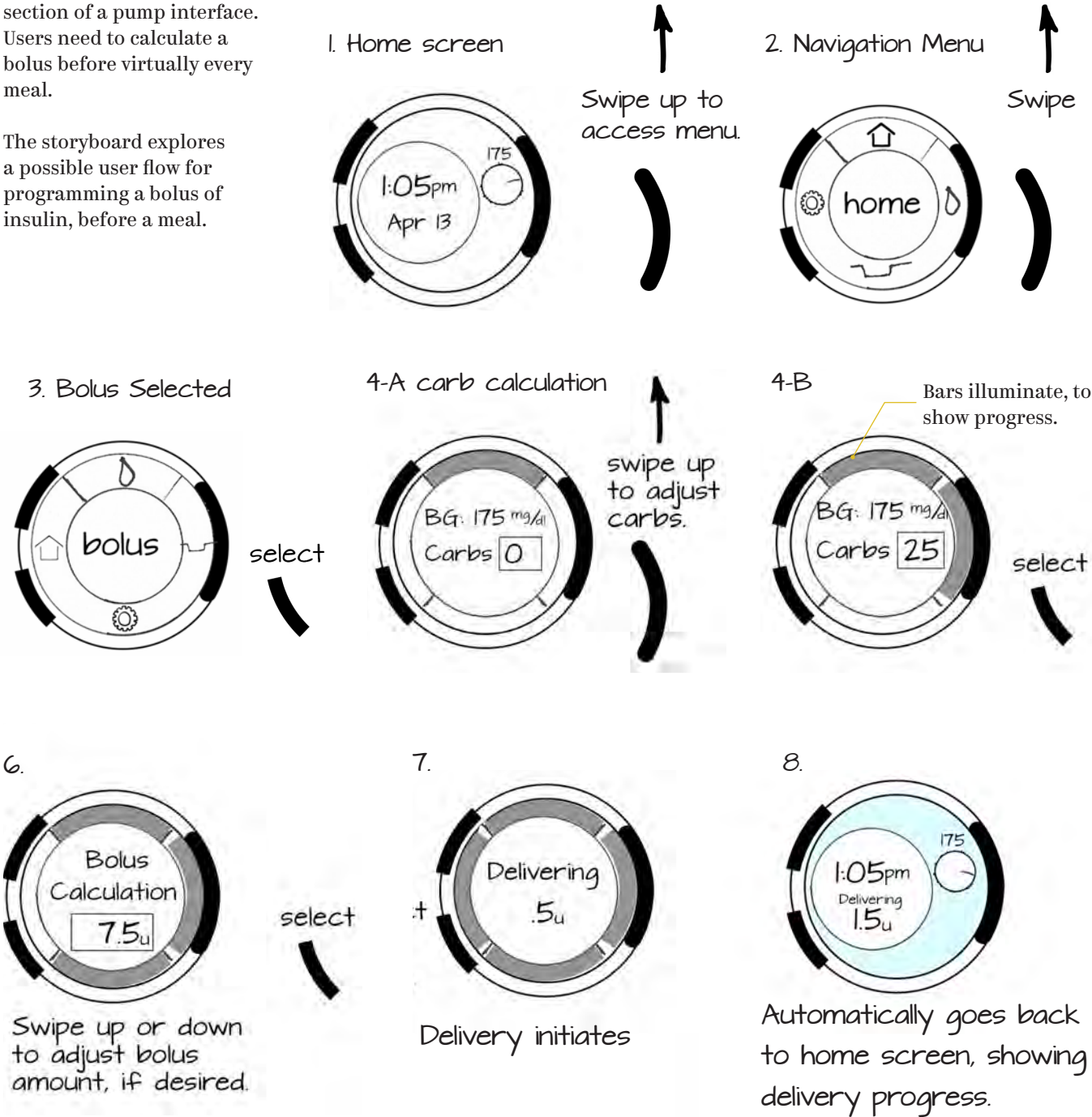
Menu

BOLUS USER FLOW

Other than the home screen, the bolus section tends to be the most commonly used section of a pump interface. Users need to calculate a bolus before virtually every meal.

The storyboard explores a possible user flow for programming a bolus of insulin, before a meal.

Bolus User Path Sketch

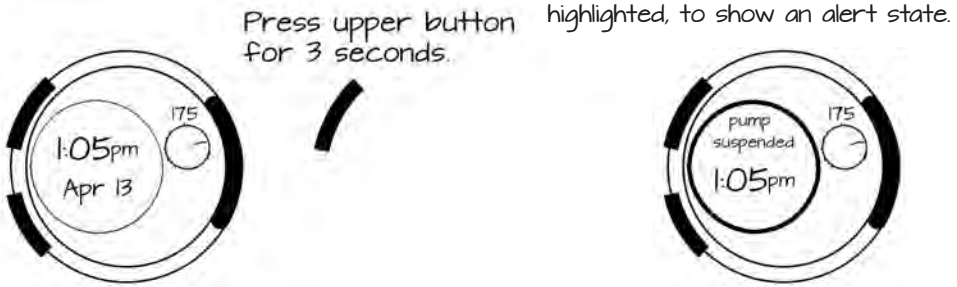


QUICK ACCESS FEATURES

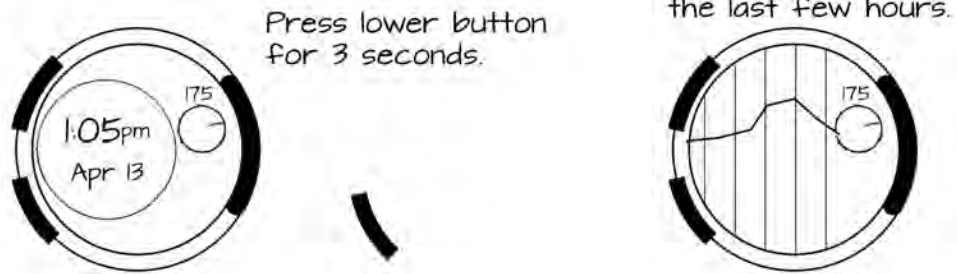
Easy access features are common for insulin pump interfaces. Most pumps have a Quick Bolus feature, which gives users a simple option for correction and meal boluses.

Suspending insulin delivery and checking glucose history are commonly performed tasks, which may also be useful in a quick access feature.

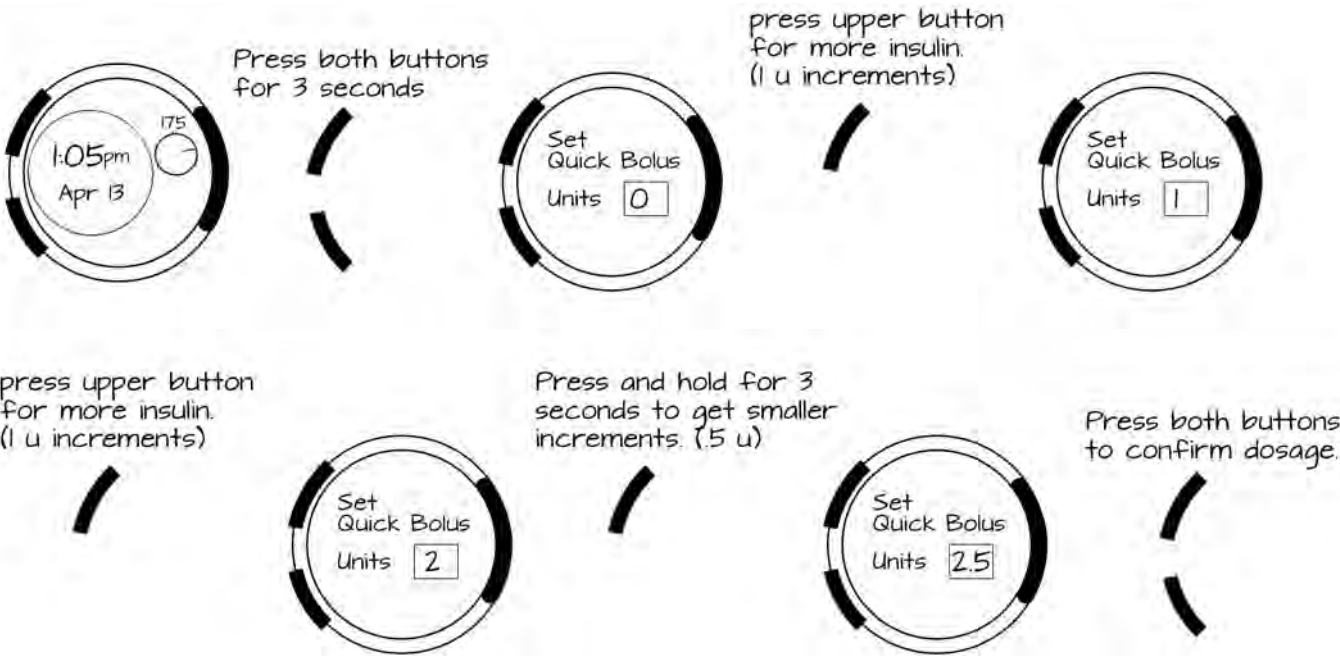
Suspend Insulin Delivery



Check Blood Sugar History



Quick Bolus Feature



INTERACTION DESIGN STRATEGY AND ECOSYSTEM

Many survey comments expressed a desire for a more efficient user flow. Statements like, “Not go through so many steps to do a simple bolus!” (R970), and “more user friendly” (R60), point to deficiencies with pump interactive design. Interview data also revealed shortcomings in the interface design. As P7 stated, “Bolus/Basal history is a very poorly organized section of the interface. Hard to tell boluses apart. No logical spreadsheet breakdowns.” With navigation being one of the more heavily discussed topics in the survey open-ended questions and in the interviews, it behooved the study to take a ground-up approach to the interface design.

The interface design strategy was developed in tandem with UI sketches. The design strategy guidelines ensure consistency in the usability of the pump UI. This set of basic principles is meant to inform how much content is available to the user at any given time, general user flow, and visual style.

A design ecosystem was also developed in order to show where the controller and pump fit into the larger ecosystem of users, stakeholders, and communications networks.

INTERACTIVE STRATEGY:
CONVENIENCE AND INTENT

Convenience and intent represent the ideal combination of ease-of-use and safe use. Processes for regular actions, like bolus, should utilize few steps to complete. In other words, convenient. On the other hand, safeguards are necessary for preventing accidents. This means the user would only give a correction bolus when he or she intends to do so. The physical interface does not use a touch screen as one safe guard. The user must swipe the scrolling pad to activate the menu, then press the select button to select menu items. This safeguard is meant to reduce the likelihood of an accidental button push causing an unintentional interaction.



Swipe the scrolling pad to activate navigation.



Pressing the select button opens up a new screen from the menu.



From the selected screen, a task can be initiated.

INTERACTIVE STRATEGY:
GLANCEABLE. ACCESSIBLE.

The wrist controller interface was designed to be glanced at on a regular basis, helping the user to have a clear picture of the state of his or her blood glucose. Since the interface is meant for glancing, information should be uncluttered and easy to interpret. Interactions should be kept simple. The amount of information present on the screen should also be limited. The dominant, sub-dominant, subordinate design principle is a helpful guideline for the number of elements present on the UI, at any given time.

Good



Dominant, Sub-dominant, and Subordinate.

Good



Dominant and Sub-dominant.

Not Good



Many elements. No clear dominance.

VISUAL DESIGN ELEMENTS

The visual elements of the controller interface are kept simple in order to ensure that the UI is as glanceable as possible. Each element serves one primary function, and is designed to provide quick interaction.

Menu Navigation

The navigation menu appears as a scrollable list. The menu item at the center of the display can be selected, leading to the next screen. Main menu items should be accompanied with graphic icons. Secondary menu items should only contain text.



Main menu



Secondary menu

CGM As A Watch Complication

The watch face screen displays a complication for the Continuous Glucose Monitor. The CGM complication provides a snapshot for the user’s blood sugar at the present time. The primary information provided is actual glucose and trajectory.



Glucose is 112 (on target) and on a steady trajectory.



Glucose is 255 (above target) and increasing at 60-90 mg/dl per 1/2 hour.



Glucose is 73 (below target) and decreasing at 30-60 mg/dl per 1/2 hour.



Glucose is 54 (severely below target) and decreasing at more than 90 mg/dl per 1/2 hour.

Glucose Trajectory Arrow

➡ Glucose remaining steady (not increasing/decreasing rapidly)

↗ ↘ Could increase/decrease between 30-60 mg/dl in 30 minutes.

⬆ ⬇ Could increase/decrease between 60-90 mg/dl in 30 minutes

⬇ ⬇ Could increase/decrease more than 90 mg/dl in 30 minutes

Non Critical Alerts

Non critical alerts represent state-changes with the system, such as temporary basal rate, delivering insulin, or delivery suspended by the user. Non critical alerts appear as a color animation of the dominant circular complication in the watch face home screen.



Default state of the watch face



Watch face showing a non-critical alert

Critical Alerts

Alerts appear as an overlay with alert message. Pressing the back button takes the UI back to the watch face, containing an alert icon. The alert also appears as the “in-focus” navigation item, when navigation is prompted.



Showing low battery alert.



Face screen showing alert icon.



Alert shows up as primary item in navigation.



Selection from navigation menu shows the alert.

Counter

The counter is used for tasks like programming a meal bolus, or manually entering a glucose level in instances when the CGM data is unavailable.



Swipe up to increase carb count from zero.

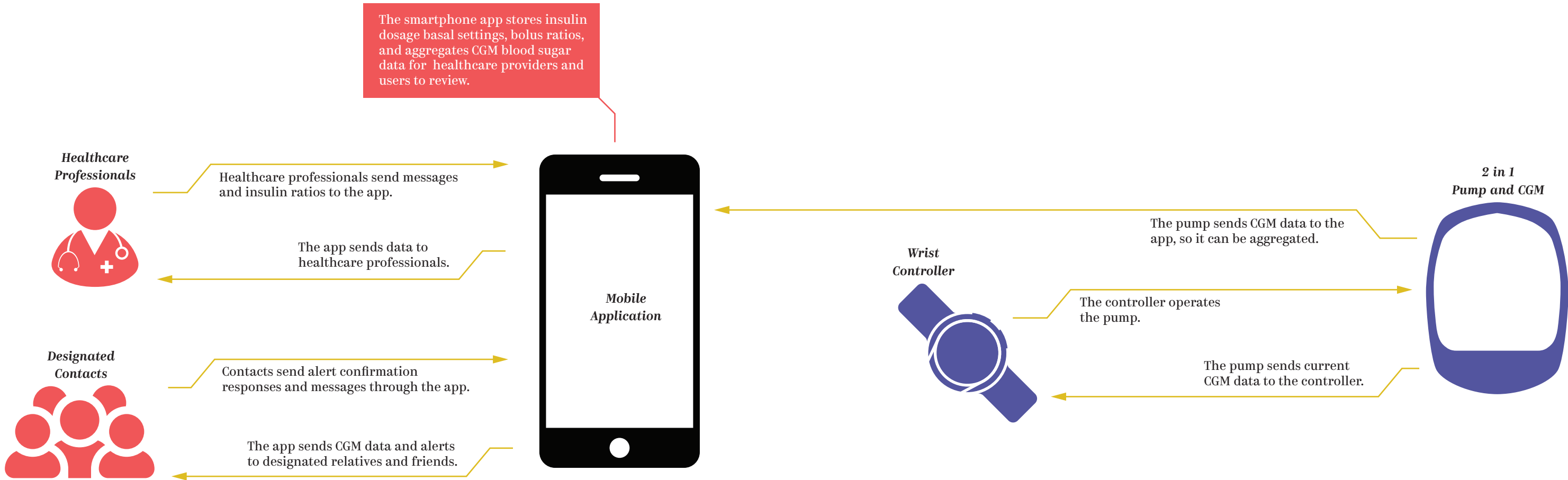


Swipe down to decrease carb count.



DESIGN ECOSYSTEM

The diagram below illustrates how the new insulin pump-CGM Wrist controller system communicates. The wrist controller operates the main functions of the pump (bolusing, suspending the pump, temporary insulin rates, monitoring current CGM data) The smartphone app, delves deeper into the operation of the system without directly controlling the pump. While the controller is primarily pump facing. The App is primarily external facing. The app's purpose is to visualize blood sugar and insulin dosage trends over time, and communicate with healthcare professionals and designated contacts.



CAD RENDERINGS AND INTERACTIVE PROTOTYPE

CAD renderings were designed, based on final sketches. Where possible, CAD files of actual components were added to each model, in order to account for internal components. The digital prototype was developed in order to test the final design.

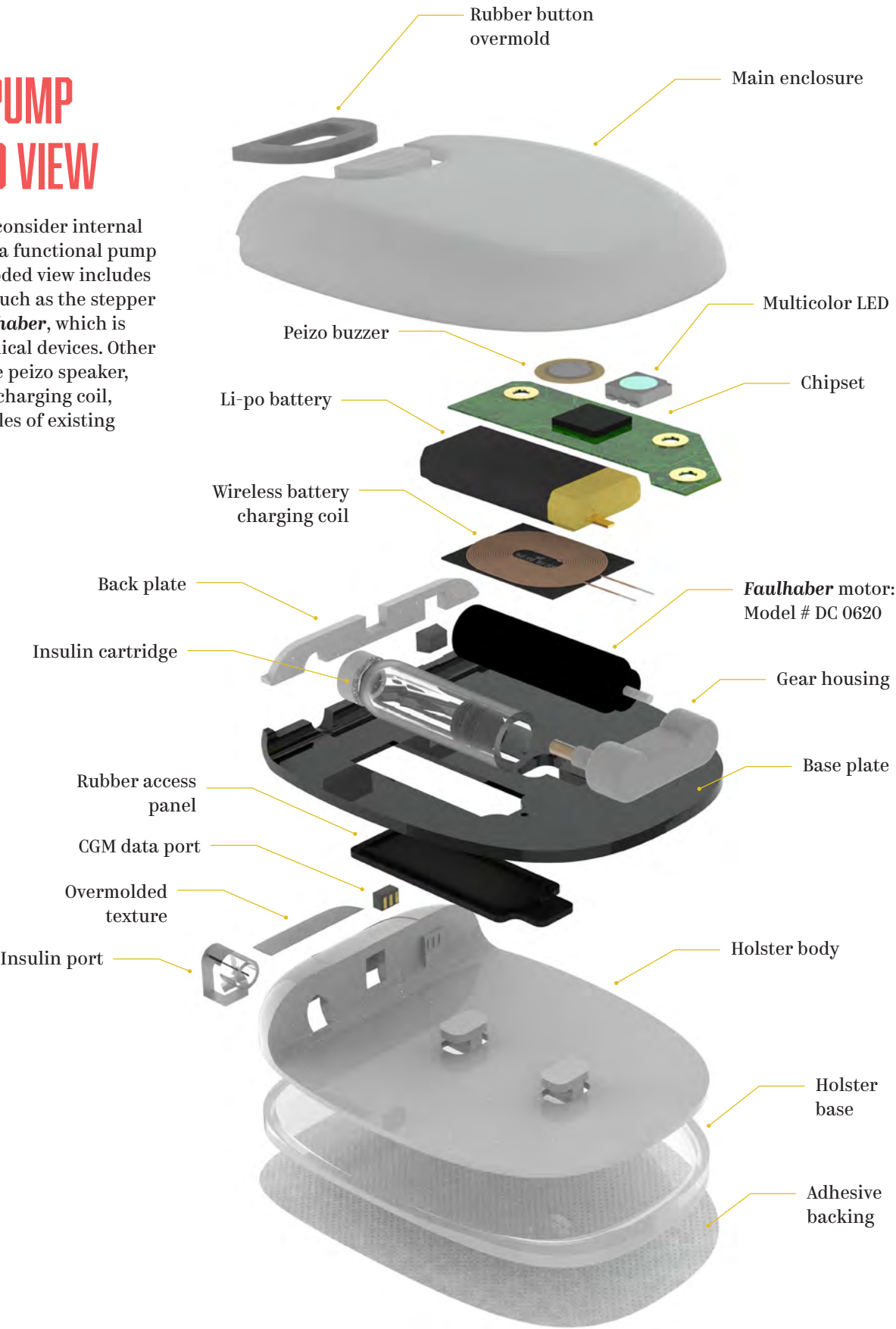
PRODUCT FAMILY RENDERINGS

The pump and controller were designed as a product family. The visual language of the white enclosures with dark accents, help tie the two artifacts together. While the rounded designs are meant to enhance wear-ability, so the devices are less likely to catch on objects, the forms also help the pump and controller to match.



INSULIN PUMP EXPLODED VIEW

It was crucial to consider internal components, for a functional pump design. The exploded view includes sourceable parts such as the stepper motor from *Faulhaber*, which is designed for medical devices. Other parts, such as the peizo speaker, LED light, and recharging coil, came from CAD files of existing products.



PUMP DESIGN ELEMENTS

The curved form of the pump was influenced by participant design PI's concept, based on the form of a river rock. This form was also strongly influenced by Gemperle's design criteria for a humanistic wearable form. (figure 12) The concave base was also incorporated to align with that study.



Fig 12, Gommerdelle's illustration of the humanistic wearable form.

Side view, showing the pump's concave base.



CONTROLLER DESIGN ELEMENTS

The unique interface feature for the wrist controller, is the capacitive trackpad, intended for simple swiping interactions. While a myriad of planar trackpads and touch surfaces exist, from laptops to touch screens, technology for a biconvex touch surface is in its early stages if not speculative. Several companies are developing in-mold electronic (IME) input devices [15, 16]. In-mold capacitive technology involves thermoforming a flexible sheet containing capacitive ink onto a three-dimensional plastic part, creating a complex form that functions as a tactile touch interface. The current intended applications for IME devices include appliances, automotive interiors, aerospace industry, and consumer electronics. While IME may be a potential solution for the trackpad, considerations need

to be made to ensure the domed design could endure thermoforming without encountering drafting and warping issues.

Attempting to prototype the controller utilizing IME would be out of scope for this study, however, the swiping interaction is testable by using several off-the-shelf components. Interactions could be tested on the watch controller by placing a flexible 12.5mm soft potentiometer [17] on a physical model. These inexpensive sensors have been used for various swiping interactions [18] for basic physical computing applications.



Profile of the controller trackpad.



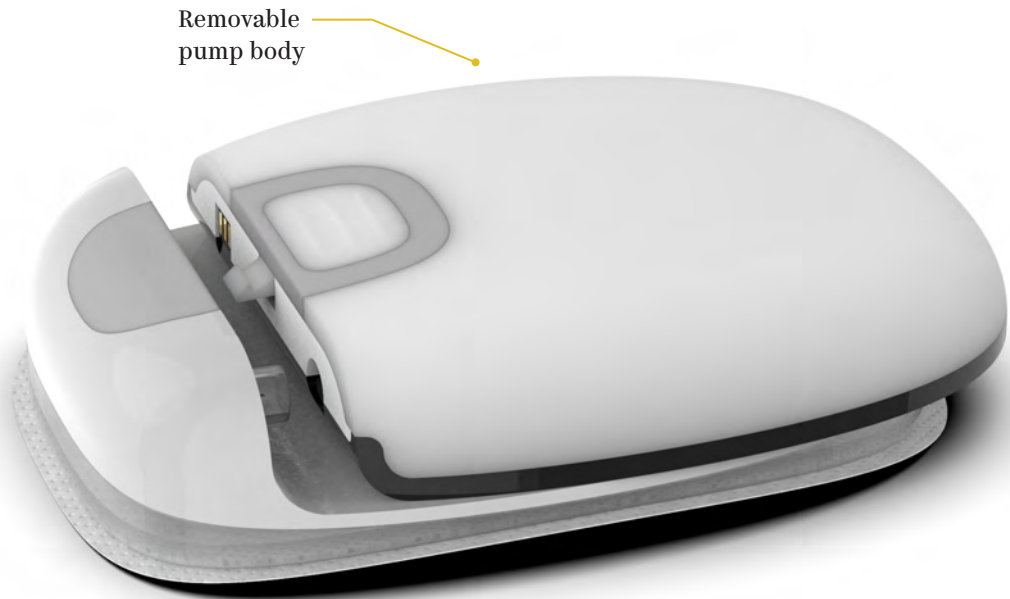
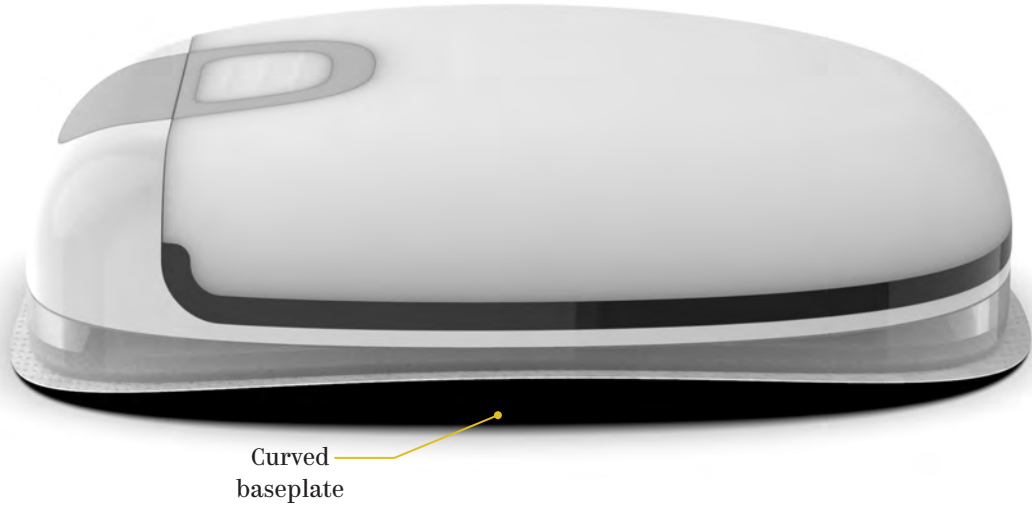
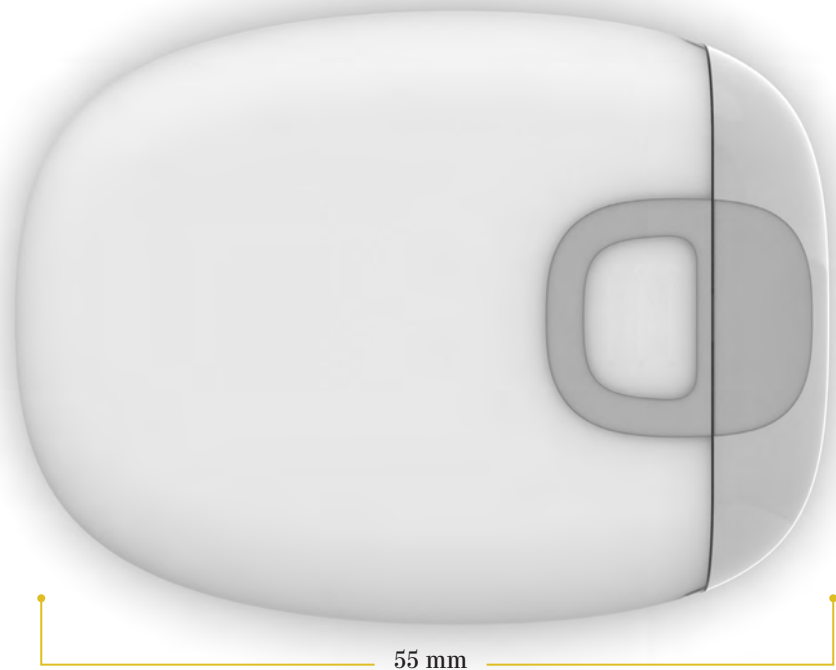
Example Soft Potentiometer [17]



Figure 13, Left: image of In-Mold-Electronics design[15] Right: Soft potentiometer being used for swipe interaction [18].

INSULIN PUMP
RENDERINGS

The following pump renderings were used during user tests. These images communicate the general size of the pump, and it's differentiating features: the curved baseplate, and refillable design.



CONTROLLER RENDERINGS

Detailed renderings of the watch controller were also designed for the purposes of user testing. The renderings are meant to help inform users on functionality of the controller's physical buttons.

Back Button

Press the back button go back one step.

The back button is Located above the selection button.



Selection Button

Located on the lower part of the controller. Press the selection button, to make selections.

Trackpad

Swiping the trackpad activates the main menu, from the main screen.

Swipe on the track pad for scrolling through menus, and adding or subtracting numbered items.



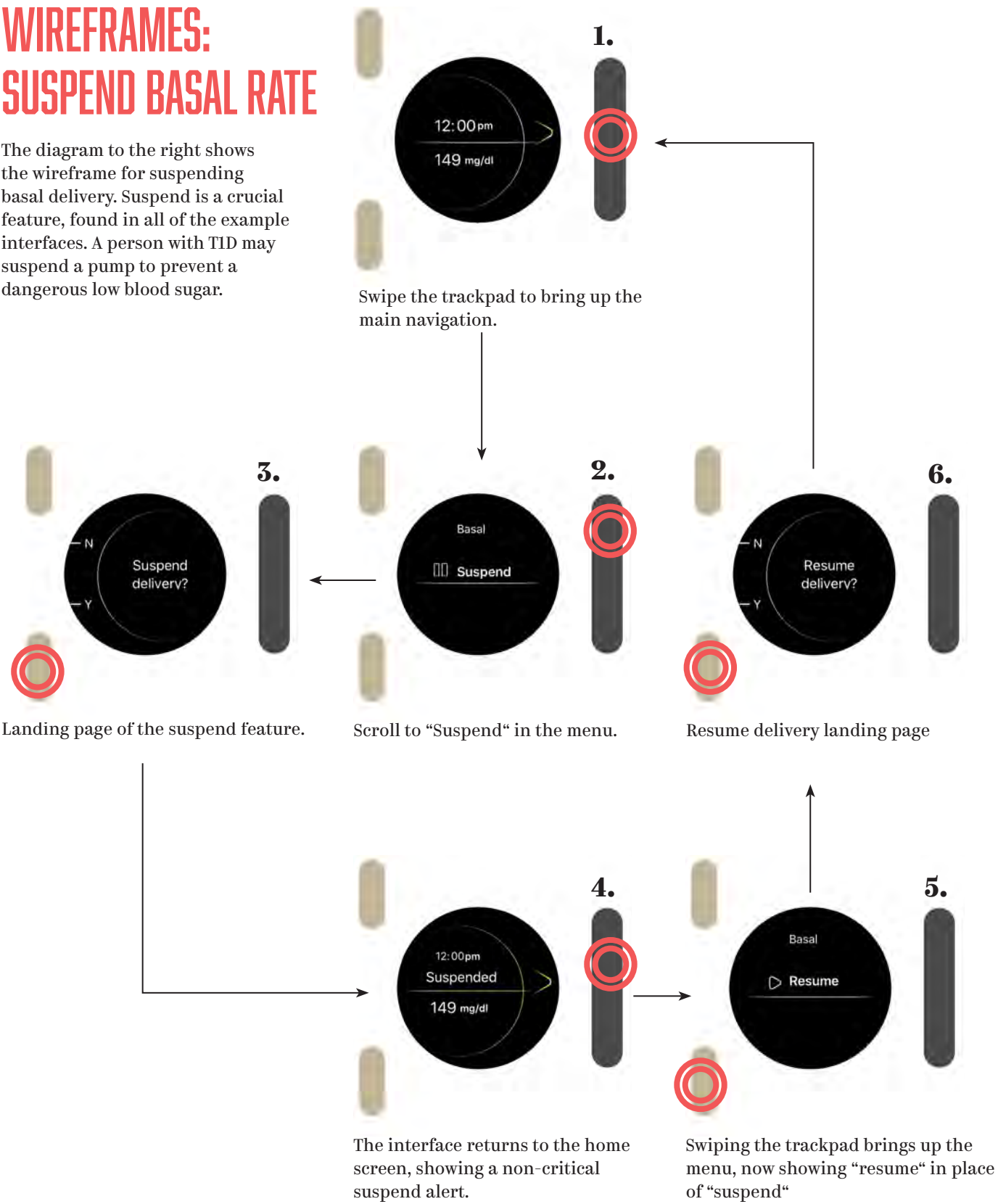
WIREFRAMES AND DIGITAL PROTOTYPING

After rough wireframes were sketched, *Protopie* was used for designing the digital prototype, to be implemented for user testing.

The prototype features user paths for three commonly used interactions; programming a bolus, suspending delivery, and programming a temporary basal rate. Several quick access features were also designed for the prototype, including CGM detail view, quick suspend, and quick bolus.

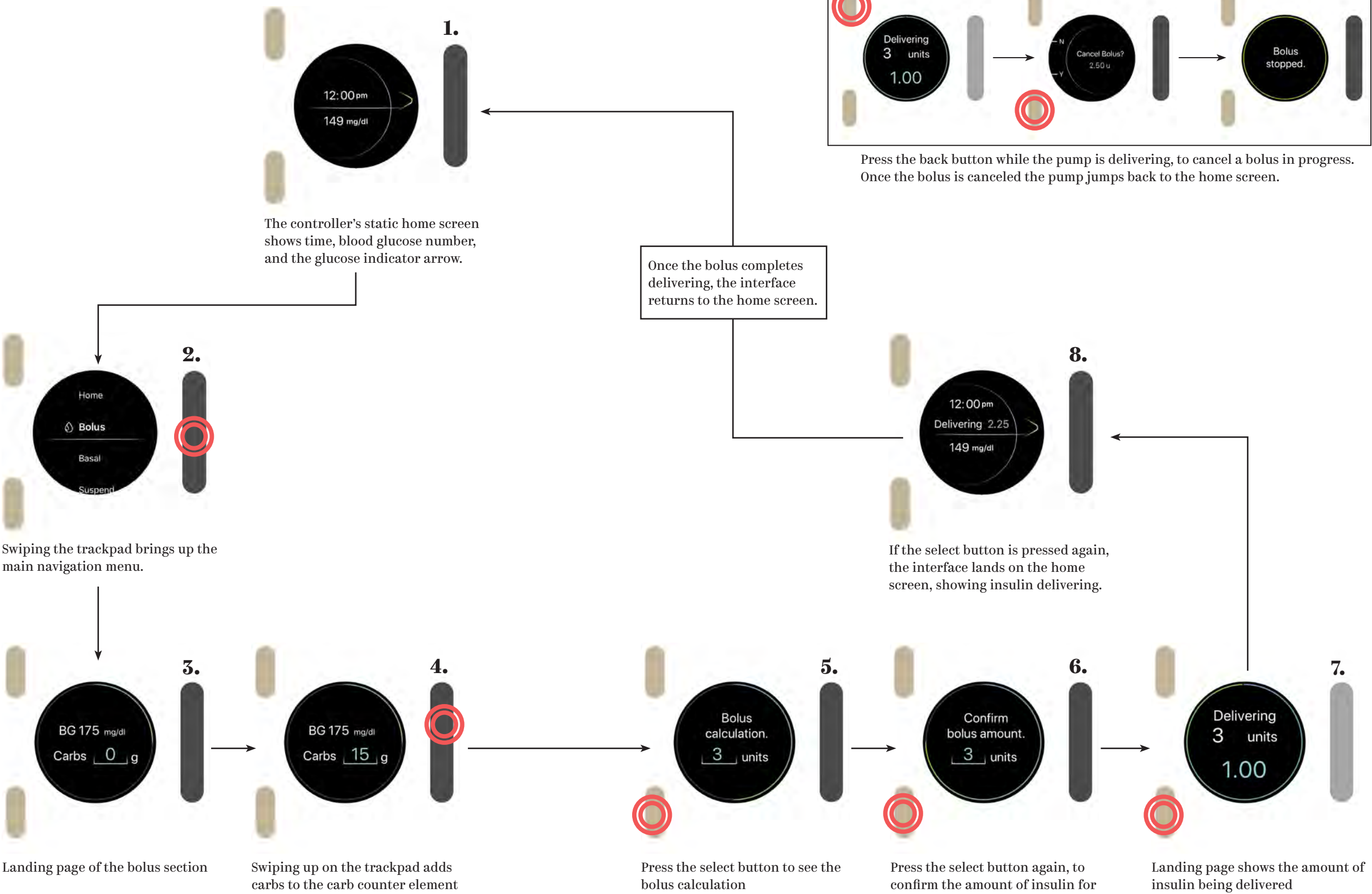
WIREFRAMES: SUSPEND BASAL RATE

The diagram to the right shows the wireframe for suspending basal delivery. Suspend is a crucial feature, found in all of the example interfaces. A person with T1D may suspend a pump to prevent a dangerous low blood sugar.



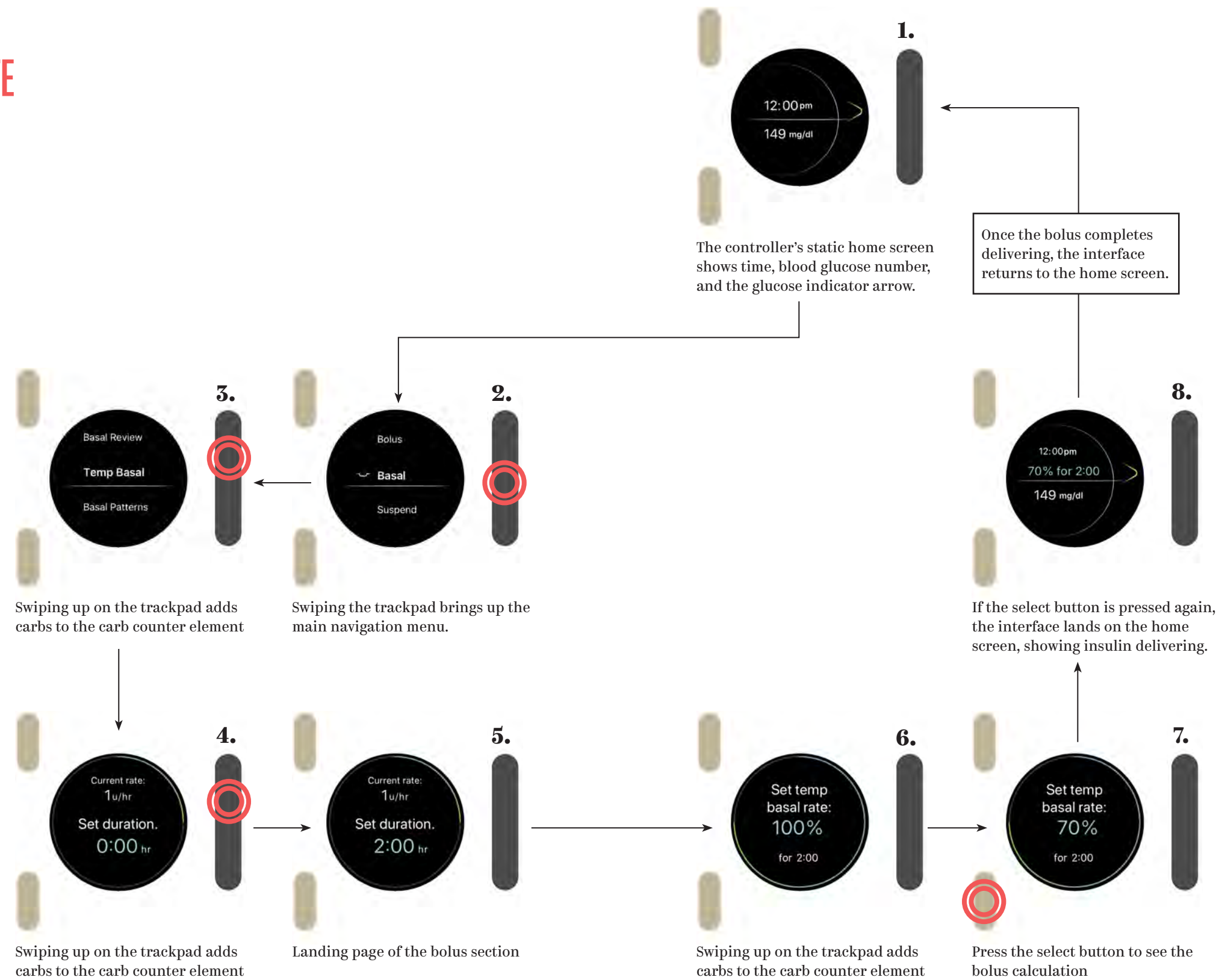
WIREFRAMES: PROGRAMING A BOLUS

The following diagram shows the wireframe for programming a bolus. A pump user needs to program a bolus before each meal. The diagram also shows the basic user path for canceling a bolus in progress. This can be useful if the bolus calculation was wrong, or if meal time is delayed.



WIREFRAMES: TEMPORARY BASAL RATE

Temporary rates are typically executed in preparation for exercise. In this wireframe, a duration is set, then the basal rate can be adjusted by a percentage.



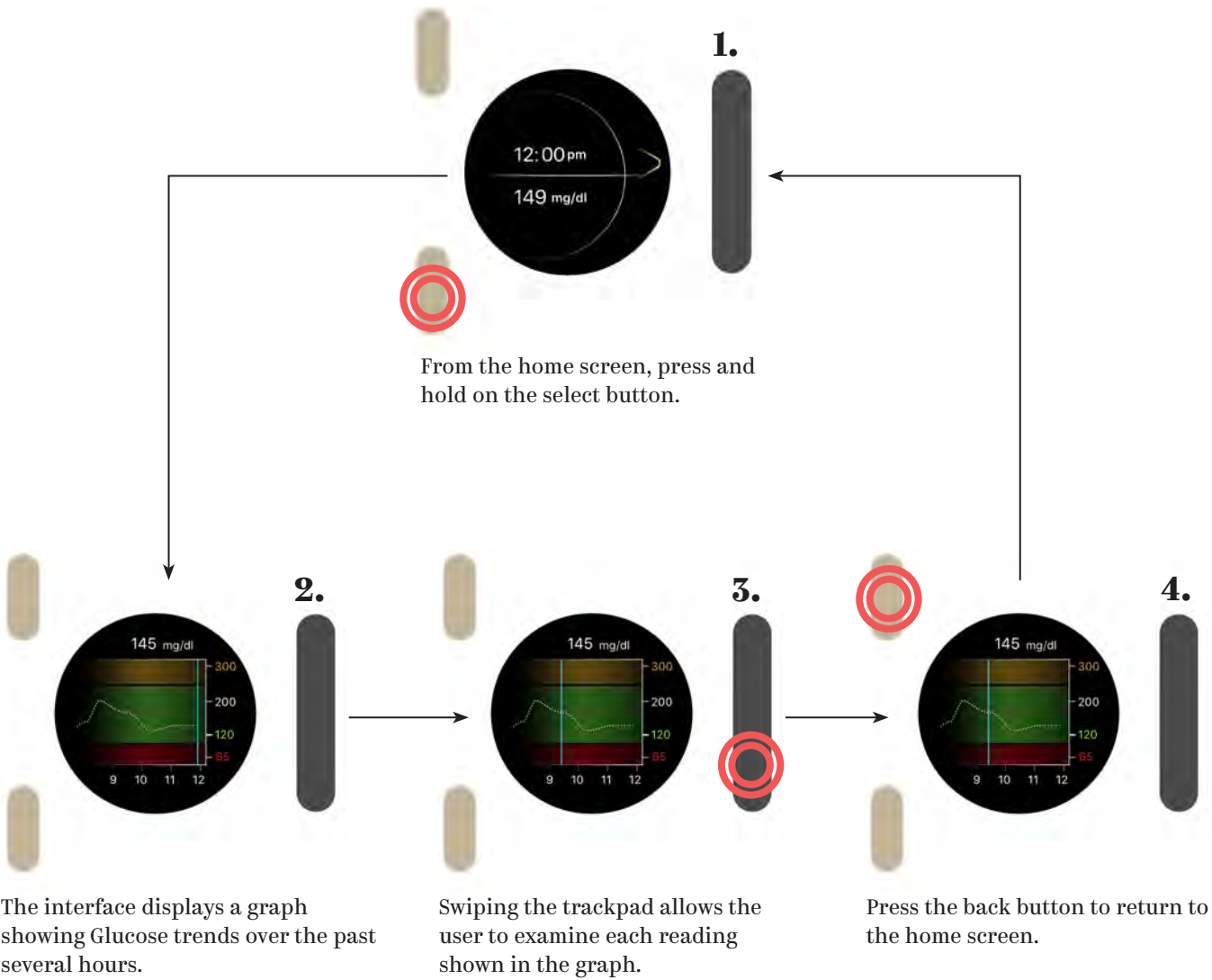
QUICK ACCESS FEATURES

Quick features were incorporated as a possible means of reducing eyes-on interaction. The quick features incorporate fewer button presses to accomplish tasks, and rely on the tactile feel of the mechanical buttons. Accessing a quick feature requires pressing and holding on the select button, back button, or both at the same time.

Another, more obvious, goal of incorporating quick features was to enable users to accomplish tasks more quickly. Faster interface task completions could reduce the number and severity of interruptions people experience while doing regular activities, such as attending social activities or exercising.

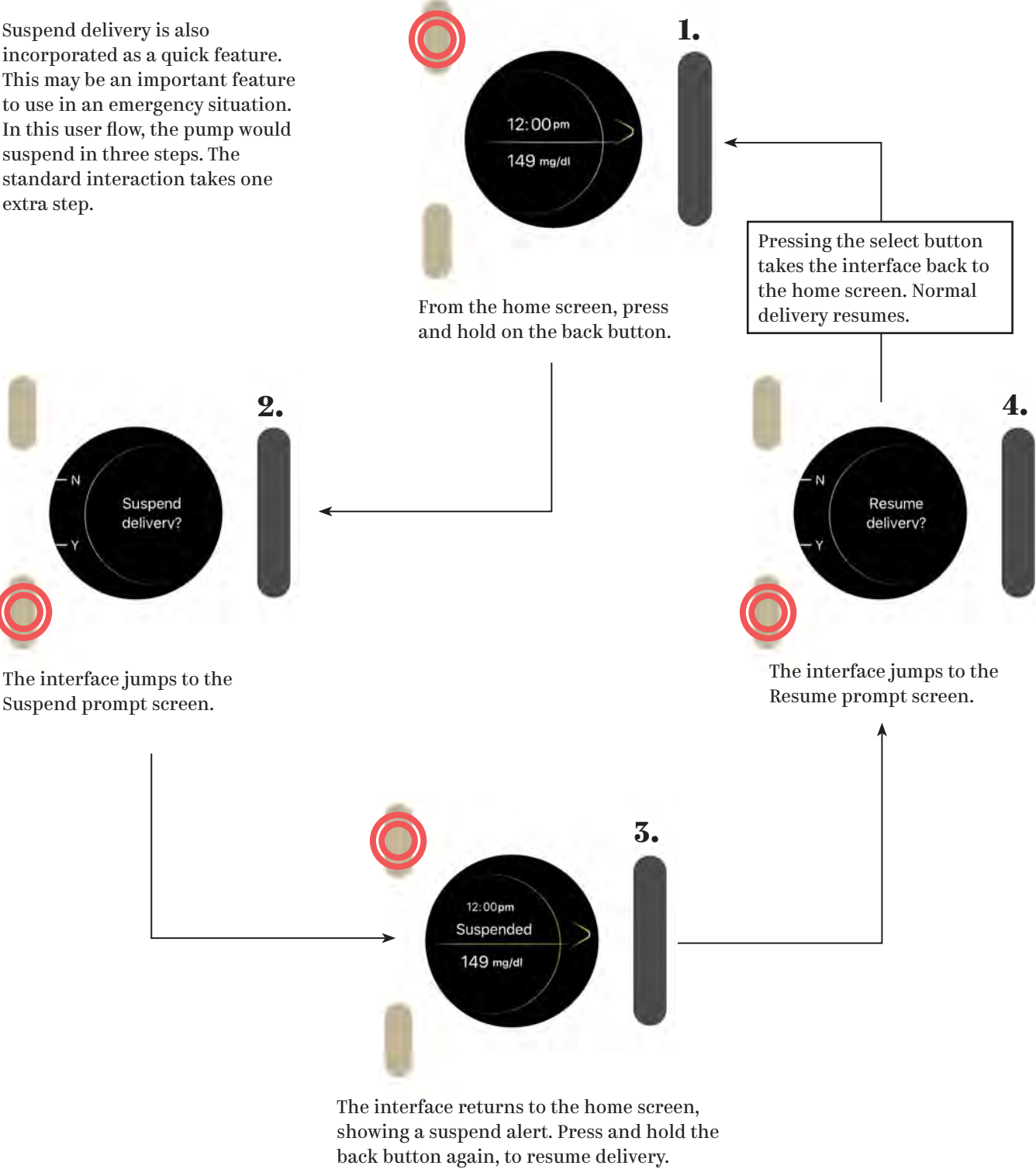
QUICK FEATURE: CGM DETAIL VIEW

The CGM graph quick feature is designed to give the user a detailed history of glucose levels over the previous several hours.



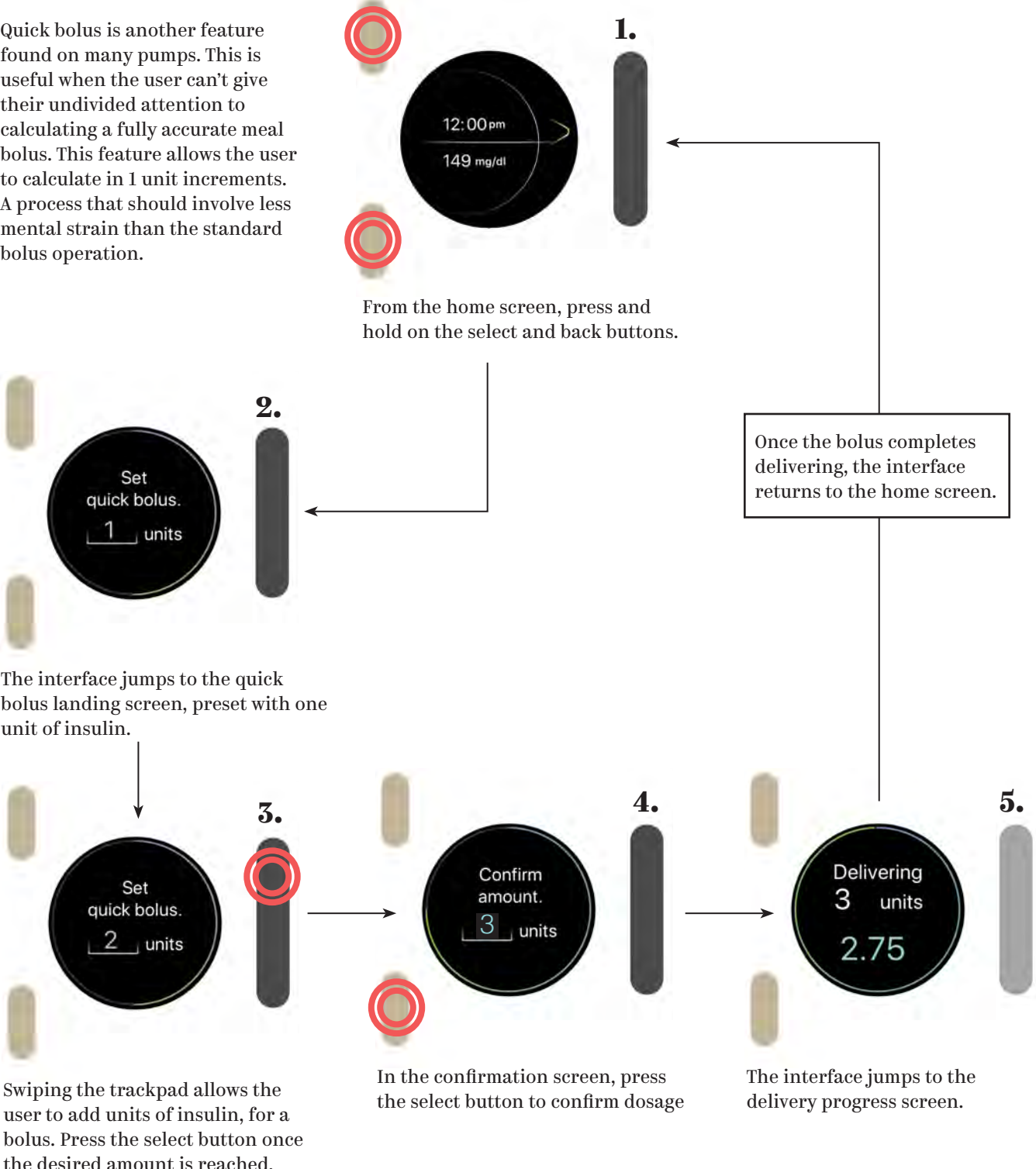
QUICK FEATURE: SUSPEND DELIVERY

Suspend delivery is also incorporated as a quick feature. This may be an important feature to use in an emergency situation. In this user flow, the pump would suspend in three steps. The standard interaction takes one extra step.



QUICK FEATURE: QUICK BOLUS

Quick bolus is another feature found on many pumps. This is useful when the user can't give their undivided attention to calculating a fully accurate meal bolus. This feature allows the user to calculate in 1 unit increments. A process that should involve less mental strain than the standard bolus operation.



PHASE IV: USER TESTING

*Evaluating CAD Renderings,
Testing the Interactive Prototype*

TESTING METHODOLOGY

Before it was time for creative development and usability tests, the Covid-19 pandemic broke out, preventing access to Ga Tech campus fabrication recourses and in-person meetings. This meant shifting from in-person tests with physical models to web-based video conferencing sessions. During the remote sessions, participants were shown CAD renderings over screen share, then interacted with a web-based interface prototype using their smartphones. A “think aloud” approach was applied for usability sessions, where participants were asked to talk through what they saw and interacted with [19]. This helped to establish a reliable communication line between tester and participant.

The goal of user testing was to evaluate acceptance and perceived usefulness of the pump/controller

design, as well as usability of the controller interface. The one-on-one remote sessions followed a three-stage structure. During stage one, participants reviewed the CAD renderings of the patch pump design concept and remote controller. During Stage two, participants completed four tasks using the interface prototype. In stage three, participants were invited to express any additional thoughts they had on the design concept. Each usability session took between 40-105 minutes to complete.

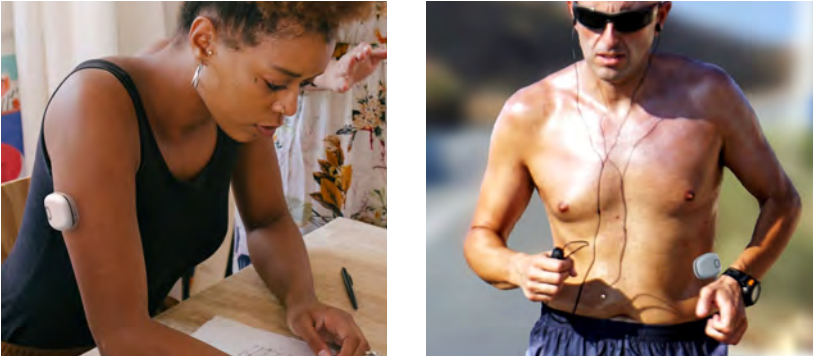
Seven participants were recruited for usability testing, through a Georgia JD RF Facebook support group, and various personal contacts. One of the participants acts as a caretaker who operates their 6-y/o child’s insulin pump. All participants reside in various counties throughout the state

of Georgia. They include six females and one male. Average age was 35-44. Occupations included event planner, executive management, teacher, retired nurse/diabetes educator, and student.

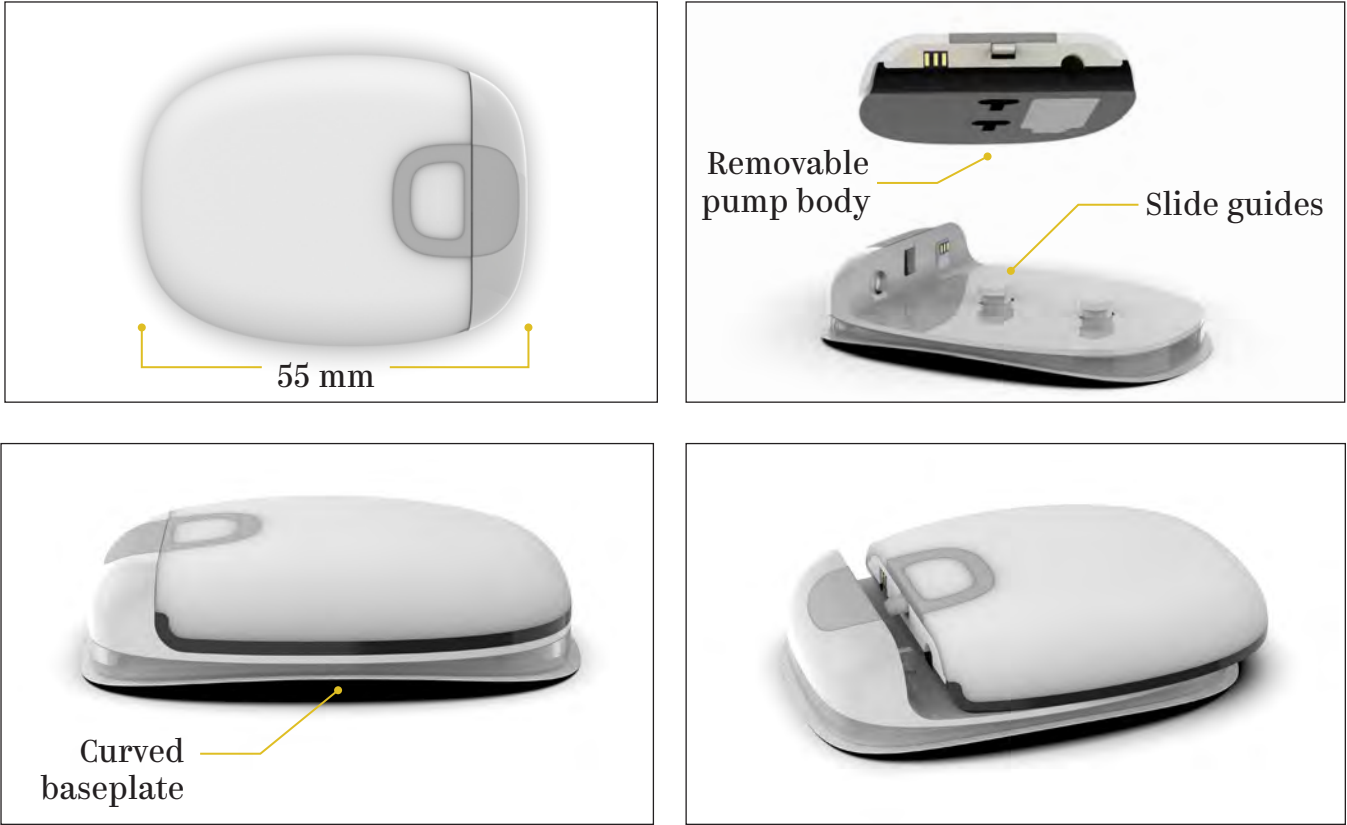
STAGE 1: CAD RENDERINGS

The below CAD renderings of the pump design were presented, which show several defining features. These features include the curve, designed to hug the body and lifestyle images (to the right) to show the scale and intended wearing locations. Storyboards showing the refilling process were then presented. Renderings of the watch controller were also reviewed, showing the button layout and lifestyle images of the watch being worn on the left or right hand.

Contextual Lifestyle Images



Pump Renderings



EVALUATING THE PUMP’S CURVE

Participant evaluations of the pump’s curve, designed for optimal wear-ability, revealed valuable insights. The chart below maps responses in a Likert scale. Those who gave the curve positive reviews, supposed it would help prevent the pump from being knocked off. P3 mentioned, “My sensor sites have come off during workouts where I’m bending and twisting, or picking up kids. I think that it could potentially allow for it to not be constantly popping off, maybe.” P2 also discussed his daughter being prone to bumping into doorways, knocking her patch-pump off. “If the profile is closer to the body, it might reduce that.” Other participants felt that body

placement and body type would need to be considered, in regard to the curve’s effectiveness. P4 commented “For people who use it on their arms and stuff, that curve would definitely be more appealing. Stomach, you could go either way, really.” P5 also mentioned that the curve’s effectiveness would depend on body type. “I definitely think there’s a lot of potential there...I’m wondering if it would vary, based on body composition/body type.” P6 expressed indifference, saying her patch pump’s footprint is so small, she often forgets she’s wearing one.

The volume of the pump design is slightly larger than the current Omnipod. While P1 didn’t have

conclusive feedback for the potential effectiveness of the curve, her assessment of the design’s wear-ability was that it may be more likely to knock off due to its larger size. Recounting her experience using a patch pump, P1 stated “I just found it annoying to have it on my arm, because I would hit it on more things. That’s the major issue with this pump, is that it’s just a bigger device.”

Assesments of the curved design.

Rating:	Hindrance	Slight Hindrance	Makes No Difference	Somewhat Effective	Highly Effective
P1	inconclusive	inconclusive	inconclusive	inconclusive	inconclusive
P2					✓
P3				✓	
P4				✓	
P5		✓			
P6			✓		
P7				✓	

EXAMINING THE REFILL PROCESS

While all participants found the refill feature to be a potentially valuable benefit, several drawbacks were foreseen. Participants were asked to infer whether this would be a simple or overly complex task, compared the process of refilling their own pumps. P2 and P3 felt the rubber access flap may be a potential weakness. P3 stated, “the rubber tab. People without fingernails might find it hard to pull.” P3 asked, “With the lifting that up and down constantly, would there be any issues that you could foresee where it could break off potentially?” P1 also felt the refilling process may be more complicated when compared to that of other patch-pumps. “The biggest thing I liked about the Omnipod is that it

was the all in one. You could just smack it on your arm, or on your stomach, and there weren’t extra pieces for it...I think the less steps in the (refill) process, the easier it will be for people.” On the other hand, P4-7, felt the refilling process could be very simple. P5 stated, “It seems super straight forward. You just fill up the vial, stick it in, and attach it back to the base site.” P4 mentioned, “It’s just automatically appealing to me because you don’t have to change a pump site. The refilling thing is a lot more convenient.”

Assessments of the refilling process

Rating:	Simple	Somewhat Simple	No More Complex than my pump.	Slightly More Complex	Overly Complex
P1					✓
P2				✓	
P3				✓	
P4	✓				
P5	✓				
P6	✓				
P7			✓		

EVALUATING THE WATCH CONTROLLER FORM

The controller was presented, showing the primary functions of the buttons. Lifestyle images of the controller being worn on the left and right hand were also shown. All participants thought the arrangement of the buttons and trackpad would be easy to interact with. P7 mentioned, “Yeah, I think it would be really easy to use. And it’s kind of like the apple watch, where you can use it on either hand. Easy to look at and get to.” In evaluating the button layout of the controller, P3 stated, “I like how you explained that the selection button is closer to you and that makes sense. The interface is something that is very simple, but

to the point that people would be able to grasp it fairly easily.” Participants also gave positive feedback in expressing their general thoughts on the controller. P3 remarked, “I definitely like a watch style option. That would be very useful. Especially trying to wear a dress, or different clothing options that you’re wearing, it’s very hard sometimes with a pump.” P2, and P6 also felt it would potentially reduce the number of devices T1D people need to carry around, as P2 mentioned, “Love the watch concept! My daughter carries a fanny pack with her monitor, extra Omnipod,

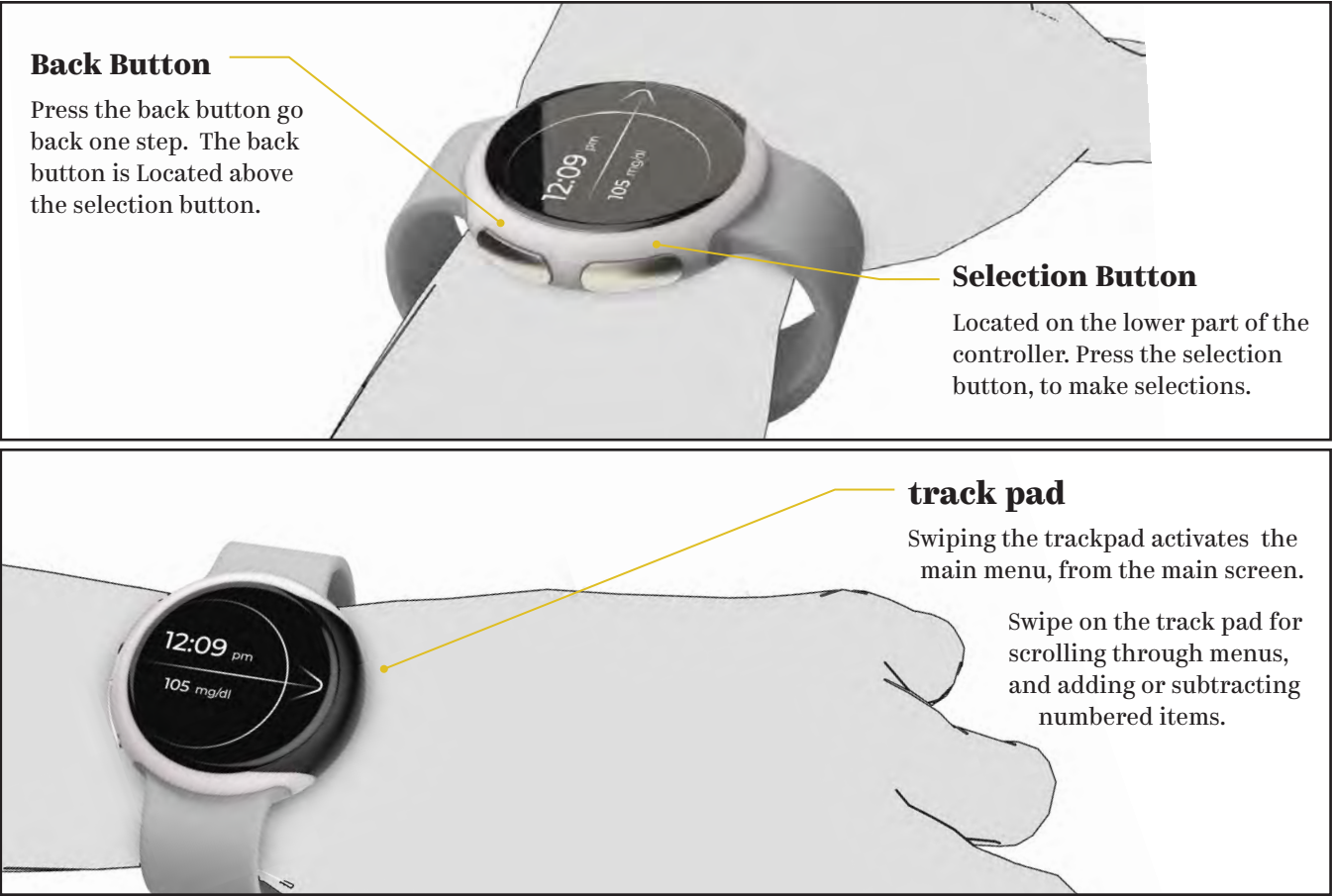
and supplies, and the Omnipod controller is too big to fit.” P6 stated, “That makes it easier to carry around. Right now, I have to carry a purse that has my PDM in it.” The watch controller was seen as a potentially convenient device for busy life situations. P3 mentioned, “I think of myself as a teacher, when I’m in the classroom and I’m working with a group of kids and my phone’s over at my desk. I’m not running back and forth grabbing my phone to check my blood sugar data. If I have it right there, that’s gonna alert me quickly if I have a problem.” P7 also thought the design might be useful for younger users, “Especially for little ones who

would use this, I think that’s a great idea. Because, then they can keep it on them and not set the controller down accidentally and then walk away and lose it.” Participants perceived two potential drawbacks of the controller design, relating to user preference and safety. P1 felt personal preference could be a factor, stating, “If you were to have it as a device that’s separate from the apple watch, you might get pushback from people wanting to buy it because they would then have 2 watches. If it doesn’t integrate with a watch that they already have.” People using a smartwatch would have to

trade the app capabilities of their current system for a model that only tells time and controls their APS, unless they want to wear two watches. In regard to personal preference, P5 thought the market saturation of smartwatches could be a positive sign for the controller, “I think it would be very convenient. Especially because most people have some sort of smartwatch.” P7 brought up a safety factor worth considering, “kids might accidentally push it. Especially if the buttons are protruding. I know, when I had the animas pump, I would hit it against things and suspend myself.” While

the interactive design strategy aims to reduce the risk of accidentally suspending or giving abolus, the controller should be tested as a physical model in order to assess any risk factors related to the physical buttons.

Watch Controller Button Functions



Contextual Images



PHASE 2: TESTING THE INTERACTIVE PROTOTYPE

Participants were given a hyperlink to the web-based interactive prototype, before each test began. Since links were sent no more than a few hours before each session, most participants were viewing the prototype for the first time. Prototype functions that were tested include evaluation of the CGM interface, programming a bolus, Suspending the pump, and evaluating the quick access features.

EVALUATING THE CGM SCENARIOS:

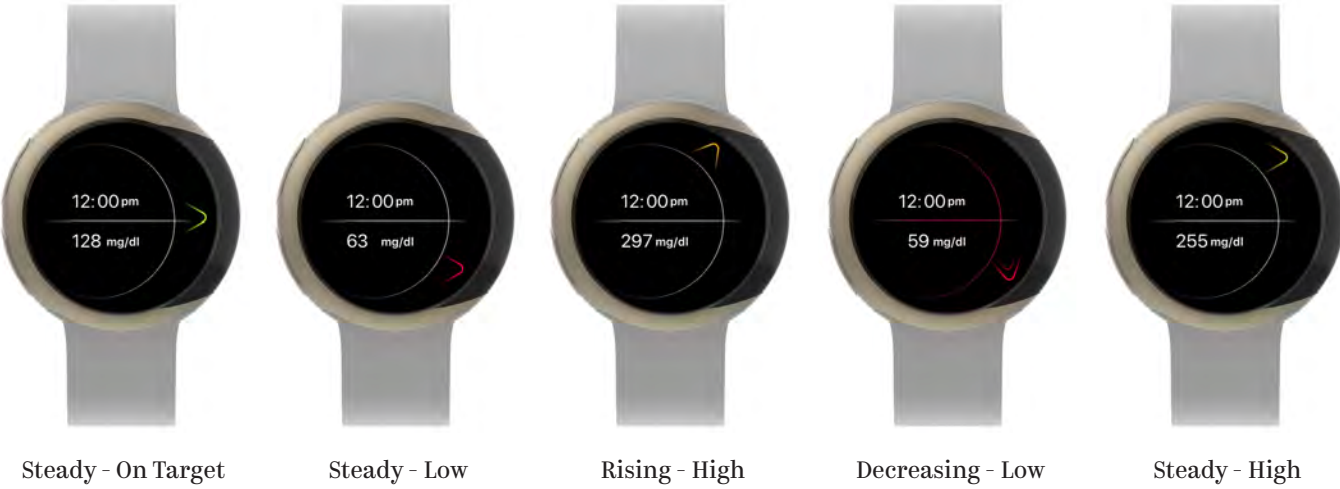
The interface's CGM indicator contains several elements that communicate glucose levels. Elements include the numerical readout, which gives the exact glucose number, and the arrow indicator which moves up or down and changes color, based on glucose levels. The arrow indicator also points up or down, based on glucose trajectory. The first task was to evaluate five different scenarios depicting different glucose levels on the prototype's CGM indicator. The figure below shows each of those scenarios.

Participants were asked to evaluate the CGM and explain what they think

the interface is communicating. All users were able to interpret the numerical readout, immediately. Participants were also able to explain arrow location and color as graphical indicators of glucose levels. As P3 stated, "If you're just glancing down at your wrist, the color would jump out at you first. Especially once you're used to wearing it. And that would give you a quick, "yeah I'm good" or, "wait. Maybe I need to look at this closer, because maybe I'm in the high or low range." While all participants also successfully interpreted the up, down, and horizontal position of the arrow as visual indicators, arrow orientation tended to be the last

thing to get noticed. P7 expressed that the direction where the arrow points to be a less obvious aspect of the interface design, "I know, like, the red arrow was in a straight line. And the green arrow was in a straight line. Now the yellow arrow is pointing up. Does that mean your blood sugar's going up?" Arrow orientation may be an aspect of the interface's visual design that needs further consideration.

Five CGM Scenarios Presented for Usability Tests



PROGRAMMING A MEAL BOLUS

The task of giving a meal bolus was subdivided into two sections. While bolusing is one of the most common interactions to perform on a pump this was the most involved task, requiring 6 steps and simple addition to complete. For the first section, participants needed to navigate to the bolus landing screen from the home screen. For the second half, they needed to calculate and deliver a meal bolus of 15 carbohydrates. This task was evaluated by measuring task completion, and number of errors that were made. 4 of 7 participants were able to complete the bolus, without instruction. Most participants gave notice when they saw that the interface was showing a “delivering bolus” status. It is thought that P4 completed the bolus section and moved on to the home screen but was the only participant not to communicate task completion of the bolus.

Only two errors were communicated while in the bolus section. P3 accidentally selected the suspend menu item and suspended insulin delivery. She was quickly able to resume delivery and go back to the bolus section, without instruction. P6 had difficulty using the trackpad. After some trial and error, she enlisted her husband for all trackpad interactions, except for adding carbohydrates. When adjusting carbohydrates, she may have held on the lower portion of the trackpad, which resulted in a bolus of -36 carbohydrates. This could have been attributed to technical difficulties. Since the prototype completely malfunctioned on P6’s smartphone, it was decided to test the interface on her desktop computer. The swipe interaction on a smartphone, then becomes a mouse click and drag action and may have been a confusing transition to make from

smartphone to desktop. Once past the trackpad interactions, P6 was able to navigate the rest of the interface, only needing one instruction to tap the selection button for completing the bolus user flow.

The prototype has an additional feature, where the user can click on the selection button while the interface is on the delivering insulin screen. Doing so takes the interface back to the home screen, where an additional element gives the status of the bolus being delivered. This is not a necessary step in delivering a bolus and wasn’t counted as a step for completing the task. However, P1 was able to complete the entire bolus user flow and go back to the home screen with bolus status element. On finding the home screen, P1 stated, “Oh, that’s nice. So, you can go back to the home screen while it’s delivering. That’s nice!”.

SUSPENDING AND RESUMING DELIVERY

Suspending then resuming insulin delivery was also subdivided into two tasks, however all participants performed this section with confidence. The only error that occurred was with P6, who enlisted her husband to use the trackpad for scrolling on two occasions. After completing this task, P1 stated, “That was easy. I think as long as it is that easy, that’s great.” In commenting on the suspend/resume functions, P7 stated, “I like how easy it is to navigate. Like, there are not a lot of options. It’s pretty straight forward.”

Potential Risks detected in Bolus and Suspend
Several participants pointed out potential risks relating to the suspend and bolus sections. There

were several comments inquiring about a lock feature, or better safeguard from accidental changes in insulin delivery. P1 described a recent incident where she accidentally gave herself a bolus while asleep, resulting in a dangerous low glucose,” I don’t remember giving myself insulin at all. On the Medtronic there is a lock function...but apparently, I got through that and gave myself insulin... and I didn’t remember anything until I woke up in the ambulance.” P7 also mentioned the physical buttons of the controller as something to consider for accidental interactions. “The only thing is kids might accidentally push it. Especially if the buttons are protruding. I know, when I had the animas pump, I would hit it against things and suspend myself.” In discussing the subject

of suspending vs. programming a temporary rate, P6 recounted her experiences as a diabetes educator: “In training patients, I never taught them to suspend. Always use a temporary basal, because I just think it’s too common for people to forget to start it back up. And then you get higher, or you go into DKA.” P5 also noted the importance of having consistent alerts for when the pump is suspended. With the prototype user flow, the suspend option shows up before the temporary basal rate. For future iterations, a safer user flow may be to give users the option to perform a temporary basal, before they get to the suspend option. It may also be worth exploring other functions to replace suspend as a quick access feature.

Bolus Completion

section:	Home	Main Menu	Bolus Screen	Enter Carbs	Bolus Estimate	Confirm Bolus	Delivering	Home - Delivering
P1	C	C	C	C	C	C	C	C
P2	I	I	I	I	C	C	C	
P3	C	C	I	C, E	C	C	C	
P4	I	C	I	C	X	X	X	
P5	C	C	C	C	C	C	C	
P6	C	C	I	C, E	I	C	C	
P7	C	C	C	C	C	C	C	

Key:
C = completed, I = completed with instruction, E = error was logged, X = didn’t complete/inconclusive

QUICK ACCESS FEATURES

The interface’s quick access features (CGM detail view and quick suspend) were tested for perceived usefulness and acceptance. The features are somewhat hidden in the interface design as Easter eggs. They aren’t accessible through the navigation menu. Instead, they are activated by pressing and holding on either the back button or select button for two seconds. Due to the concealed nature of these features, participants were simply told to press and hold either of the buttons and interpret what they see.

In accessing the quick suspend feature, P1 stated, “If you’re going low and you need to suspend, it makes sense to have that.” P3 described the interaction for the quick suspend feature, “I like how you have to hold (the button down), so you’re not going to accidentally get yourself into a situation where you’ve suspended your insulin.” P6 discussed the safety factors that could go into suspending delivery, “There’s nothing wrong with suspending, as long as you’ve got an alarm that’s going to let you know...’You’ve turned me

off, and now you’re 200!’” While the interface prototype features haptic responses for suspend, and several other interactions, the variation in how each participant setup their smartphone was too wide to be able to reliably test haptics. P3 was able to follow all necessary steps in order to get haptic responses working for the prototype. She only perceived one of about 6 prototype interactions that give a vibration response.

The CGM detail view graph was the second quick access feature to be tested. Many participants noted that having a CGM detail history is an integral feature. P2 stated, “The graph is something I would use frequently. I bolus based on graph trends.” P6 also stated, “I like to look at that. I kind of like to look for where I came from and where I’m at.” From a purely aesthetic perspective, P7 stated, “Ooh! That looks better than my graph!” Several participants asked if the high and low threshold points of the graph could be set to the user’s preference, as in other popular closed loop systems.

DISCUSSION AND FURTHER WORK

The original aim of this study was to design an insulin pump interface that allows for enhanced discreet and eyes-free operation, in order to reduce feelings of insecurity and interruptions among pump users. Adopting a user-centered investigative methodology, we found that many people experience feelings of insecurity and inconvenience while using pumps in public settings or performing demanding tasks. We uncovered several other significant issues, including wear-ability challenges that limit pump and clothing options for women, and pain points in keeping track of multiple devices which must be carried at all times. Participants expressed hardships, bumping into objects and pulling the pump tubing out, or dislodging the entire patch pump. Lastly, we found shortcomings in pump interface designs. People mentioned having to take an excessive number of steps in order to complete tasks, and frustration in dealing with alerts. Some users also found informational screens, like the bolus history, difficult to interpret. Taking all of these insights into account, we were able to design relevant potential solutions.

The usability testing insights indicated that this insulin pump concept shows potential as a refillable patch pump. Further testing needs to be done in order to reveal the effectiveness of the curved design for enhanced wear-ability and reduced dislodging, however study participants welcomed the idea of a patch pump that offers refilling capabilities. While several participants found that the refilling process could be simplified to make the design more appealing, the overall pump design was well

recieved. P6 stated, “With all you’ve got now, it looks like a great concept. You might hook up with another company that could help you to fruition”. Several other participants requested to stay in contact regarding further developments with the pump and controller concept.

Participants showed acceptance of the watch controller as a highly wearable device, imagining it would reduce the number of devices one must carry around. It was also viewed as a convenient option for interaction, since it is primarily worn on the hand and not stored in a pocket or purse, making it readily accessible. Even though the controller design is a novel concept for a pump interface, participants felt it would be acceptable to wear, given the current market saturation of smartwatches.

The interactive design strategy helped to ensure that the pump interface remained consistent throughout the whole user experience. This was one of the factors that lead to a more successful set of usability tests. Participants performed most interface tasks quickly and without making mistakes. After using the unique trackpad feature once or twice, all but one participant became proficient in using it for scrolling menus and adjusting numbered items. Many participants were vocal that the interface was simple to navigate and gave favorable reviews of the quick access features. The interface wasn’t without issues, though. The CGM was less effective at communicating glucose trajectory, by changing orientation. The interface should also be reassessed for risk factors, such as accidentally giving

a bolus or suspending the pump. Testing the current haptic feedback interactions of the interface may also lead to valuable insight, once in-person usability sessions become a viable method. It was originally hoped that haptic features would prove effective at allowing discreet eyes-free interaction. Unfortunately, it was nearly impossible to test haptic features reliably, during the remote sessions. While the current prototype features several haptic interactions, participant 3 was the only person able to activate vibration on her device, which only gave haptic feedback once. There is also room for design exploration on a safety lock feature which would disable the interface, to prevent accidental interactions.

In working with people during multiple phases of the design process, it was apparent that there are gaps between an ideal pump experience, and the experiences that many current technologies offer. A user-centered approach, such as the one used in this study, could help to bridge that gap. I personally found that the interface’s CGM design could have been improved if I had reviewed early sketches with pump users, before moving into the higher fidelity designs. While this oversight led to a design flaw, it points to the benefits of incorporating users in the design process. The hope of this project is to help convey the importance of incorporating the input from people who depend on insulin pumps. Building on the current industry’s user-centered approaches may lead to valuable innovations in diabetes management technologies.

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